

# EXHIBIT 1

Joseph M. Carbone, M.D.

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC ) Master File No.  
REPAIR SYSTEM PRODUCTS ) 2:12-MD-02327  
LIABILITY LITIGATION ) MDL 2327

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THIS DOCUMENT RELATES TO  
PLAINTIFFS:

Diane Kropf  
Case No. 2:12-cv-01202

JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE

Judy Williams  
Case No. 2:13-cv-00657

Myra Byrd  
Case No. 2:12-cv-00748

Angela Coleman  
Case No. 2:12-cv-01267

Susan Thamen (Reeves)  
Case No. 2:12-cv-00279

Donna Zoltowski  
Case No. 2:12-cv-00811

DEPOSITION OF JOSEPH M. CARBONE, M.D.

GENERAL TVT

Wednesday, March 16, 2016

Danville, Virginia

5:18 p.m.

Reported by: Karen K. Kidwell, RMR, CRR, CLR

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Joseph M. Carbone, M.D.

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<p>1 DEPOSITION of JOSEPH M. CARBONE, M.D.,  2 General TVT, a witness in the above-entitled action,  3 taken on behalf of Plaintiffs, pursuant to the  4 Federal Rules of Civil Procedures before KAREN K.  5 KIDWELL, RMR, CRR, a Certified Shorthand Reporter, at  6 Holiday Inn Express, 2121 Riverside Drive, Danville,  7 Virginia, the 16th day of March, 2016, at 5:18 p.m.</p> <p>8  9 APPEARANCES  10  11 ON BEHALF OF PLAINTIFFS:  12 WAGSTAFF &amp; CARTMELL LLP  13 Nate Jones, Esq.  14 Andrew N. Faes, Esq.  15 4740 Grand Avenue, Suite 300  16 Kansas City, MO 64112  17 816.701.1100  18 njones@wcllp.com  19 afaes@wcllp.com</p> <p>20  21 ON BEHALF OF DEFENDANTS ETHICON and  22 JOHNSON &amp; JOHNSON:  23 BUTLER SNOW, LLP  24 Paul S. Rosenblatt, Esq.  25 1020 Highland Colony Parkway  Suite 1400  Ridgeland, Mississippi 39157  601.985.4596  paul.rosenblatt@butlersnow.com</p> <p>and</p> <p>TUCKER ELLIS LLP  Matthew P. Moriarty, Esq.  950 Main Avenue, Suite 1100  Cleveland, OH 44113  216.592.5000  matthew.moriarty@tuckerellis.com</p>	<p>1 WEDNESDAY, MARCH 16, 2016, DANVILLE, VIRGINIA</p> <p>2 PROCEEDINGS</p> <p>3 -oOo-</p> <p>4 JOSEPH M. CARBONE, M.D.</p> <p>5 being first duly sworn, testified as follows:</p> <p>6 EXAMINATION</p> <p>7 BY MR. JONES:</p> <p>8 Q. Dr. Carbone, my name is Nate Jones. I  9 represent the Plaintiffs in this matter. Have you  10 given a deposition before?</p> <p>11 A. Yes, I have.</p> <p>12 Q. Are you familiar with how a deposition  13 generally proceeds throughout the time allotted?</p> <p>14 A. Generally, yes.</p> <p>15 Q. It's a question-and-answer system. I ask  16 questions; you provide the answers. If there's any  17 questions that I ask that you don't understand,  18 please tell me, and I'll do my best to rephrase the  19 question.</p> <p>20 Throughout the day I'll probably ask some  21 very poorly worded questions. So just do me a favor,  22 bear with me, be patient, and I'll do my best to  23 rephrase those in a way that might be better worded.</p> <p>24 A. Likewise.</p> <p>25 Q. Okay. You are under oath. You understand</p>
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<p>1 INDEX</p> <p>2 WITNESS/EXAMINATION Page</p> <p>3 JOSEPH M. CARBONE, M.D.</p> <p>4 By Mr. Jones 4</p> <p>5</p> <p>6 EXHIBITS</p> <p>7 Number Description Page</p> <p>8 Carbone 1 Notice to Take Deposition of .....5  Joseph Carbone M.D.</p> <p>9</p> <p>10 Carbone 2 Expert Report of Joseph .....5  Carbone, M.D. as it relates to  Wave 1 TVT Cases</p> <p>11</p> <p>12 Carbone 3 Curriculum Vitae of Joseph M. ....6  Carbone, M.D.</p> <p>13 Carbone 4 Joseph Carbone Reliance List, .....7  in Addition to Materials  Referenced in Report, MDL Wave 1</p> <p>14</p> <p>15 Carbone 5 Joseph M. Carbone, MD, .....8  Payments from Ethicon, 14  pages</p> <p>16</p> <p>17 Carbone 6 Joseph M. Carbone, Invoices .....24  for Consulting Services, 4  pages</p> <p>18</p> <p>19 Carbone 7 Yellow piece of paper, .....139  placeholder for Flash drive,  Dr. Carbone's files (marked  but not referred to)</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 that, correct?</p> <p>2 A. Yes, I do.</p> <p>3 Q. We'll start off with some of the materials  4 that we've marked as exhibits for the record.  5 (Carbone 1 was marked for identification.)</p> <p>6 BY MR. JONES:</p> <p>7 Q. Exhibit 1 is the notice to take  8 deposition. Have you seen this document before?</p> <p>9 A. I believe it was sent to me earlier today,  10 yes.</p> <p>11 Q. Great. Thanks.  12 (Carbone 2 was marked for identification.)</p> <p>13 BY MR. JONES:</p> <p>14 Q. Exhibit 2 is your expert report Wave 1,  15 TVT cases. I'll hand that to you. Do you recognize  16 that as the report you drafted for the TVT line of  17 products in this litigation?</p> <p>18 A. Without going through it line by line.</p> <p>19 Q. Yeah.</p> <p>20 A. Yes, I do.</p> <p>21 Q. And then I believe that you signed this  22 report; is that correct? Your signature?</p> <p>23 A. Not this report.</p> <p>24 Q. Okay.</p> <p>25 A. But a report similar to it.</p>

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<p>1 Q. That is your report?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. You drafted that report?</p> <p>4 A. Yes.</p> <p>5 Q. Did you have any assistance drafting that</p> <p>6 report?</p> <p>7 A. No.</p> <p>8 Q. No?</p> <p>9 A. I drafted the report.</p> <p>10 Q. Did you type that report?</p> <p>11 A. Yes, I did.</p> <p>12 (Carbone 3 was marked for identification.)</p> <p>13 BY MR. JONES:</p> <p>14 Q. Did you -- I'll go ahead and mark now</p> <p>15 Exhibit 3 which is your CV. You already have a copy?</p> <p>16 A. Is it the same?</p> <p>17 Q. You can hold on to that. It's the same</p> <p>18 one.</p> <p>19 A. Okay. And this is the same one here.</p> <p>20 Q. Right.</p> <p>21 A. Do you want to get this back?</p> <p>22 Q. You can have it.</p> <p>23 A. Two copies.</p> <p>24 Q. Yeah, more copies for you.</p> <p>25 MR. MORIARTY: Nate, I don't mean to</p>	<p>1 what is your understanding of what is included on</p> <p>2 that reliance list marked as Exhibit 4?</p> <p>3 A. They're the materials that I reviewed in</p> <p>4 preparation for this deposition.</p> <p>5 Q. Sure. So if an attorney like myself wants</p> <p>6 to go and look at the materials that you're relying</p> <p>7 on in this case for your opinions, I should go and</p> <p>8 look at the reliance list marked as Exhibit 4,</p> <p>9 correct?</p> <p>10 A. Yeah.</p> <p>11 Q. Okay. Is Exhibit 5 you brought with you</p> <p>12 today, and it's titled "Joseph M. Carbone M.D.,</p> <p>13 Payments from Ethicon." I'm going to hand that to</p> <p>14 you. It's only one copy. Did I read that correctly,</p> <p>15 the title of Exhibit 5?</p> <p>16 A. Yes.</p> <p>17 (Carbone 5 was marked for identification.)</p> <p>18 BY MR. JONES:</p> <p>19 Q. And is it your understanding that the</p> <p>20 table presented in Exhibit 5 represents the total</p> <p>21 amount of payments Ethicon has paid you as a</p> <p>22 consultant?</p> <p>23 MR. MORIARTY: Objection.</p> <p>24 THE WITNESS: Could you rephrase?</p> <p>25</p>
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<p>1 interrupt you so early, but you just reminded me</p> <p>2 of something with this Exhibit 1. There is a</p> <p>3 case on here that I don't think is his case. He</p> <p>4 did not write the case-specific report in the</p> <p>5 Zoltowski case.</p> <p>6 MR. JONES: Is he a general expert -- is</p> <p>7 he a general expert in that case? He is.</p> <p>8 That's why that case is on there. But I get</p> <p>9 you. He didn't draft the case-specific. Thanks</p> <p>10 for pointing that out. He is a general expert.</p> <p>11 Here's the reliance list, marked as</p> <p>12 Exhibit 4.</p> <p>13 (Carbone 4 was marked for identification.)</p> <p>14 BY MR. JONES:</p> <p>15 Q. Okay. Do you recognize this?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. Did you prepare that reliance list?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Did you type up that reliance list?</p> <p>20 A. No.</p> <p>21 Q. Who typed up that reliance list?</p> <p>22 A. Legal counsel.</p> <p>23 Q. Okay. But you did prepare that?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. And those -- what is it that --</p>	<p>1 BY MR. JONES:</p> <p>2 Q. Sure. What does Exhibit 5 represent?</p> <p>3 A. The 1099 -- the 1099s from Ethicon.</p> <p>4 Q. Okay. And Exhibit 5 represents the amount</p> <p>5 of payments you received from Ethicon by year acting</p> <p>6 as a consultant other than litigation consulting</p> <p>7 work, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And on some of these columns on</p> <p>10 Exhibit 5, it says, "Do not have 1099."</p> <p>11 Is it your understanding that you've</p> <p>12 looked and Ethicon has looked and the 1099 can't be</p> <p>13 found for those years?</p> <p>14 MR. MORIARTY: Objection. Form.</p> <p>15 THE WITNESS: I've looked for the 1099s.</p> <p>16 BY MR. JONES:</p> <p>17 Q. You've looked for those 1099s and you</p> <p>18 can't find them?</p> <p>19 A. That is true.</p> <p>20 Q. You don't know one way or the other</p> <p>21 whether Ethicon has looked for those 1099s?</p> <p>22 A. I don't know one way or the other.</p> <p>23 Q. Have you asked Ethicon for this</p> <p>24 information?</p> <p>25 A. I have not.</p>

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<p>1 Q. Have you asked Ethicon at all to help you</p> <p>2 tally the total amounts of payments they've paid you</p> <p>3 as a consultant outside of litigation?</p> <p>4 A. I have not.</p> <p>5 Q. So this is just the work that you've done?</p> <p>6 A. Yes.</p> <p>7 Q. And you haven't asked anybody else to</p> <p>8 assist you with this?</p> <p>9 A. I asked my wife and my accountant.</p> <p>10 Q. But not Ethicon?</p> <p>11 A. Yup.</p> <p>12 Q. Okay. If we wanted to fill in some of</p> <p>13 this missing information that you don't have 1099s</p> <p>14 for, do you think Ethicon would have that information</p> <p>15 on file?</p> <p>16 MR. MORIARTY: Objection.</p> <p>17 THE WITNESS: I wouldn't know.</p> <p>18 BY MR. JONES:</p> <p>19 Q. You wouldn't know? Every time you got</p> <p>20 paid for Ethicon, did you invoice Ethicon?</p> <p>21 A. To the best of my recollection, yes.</p> <p>22 Q. Okay. And so Ethicon, then, would have</p> <p>23 those invoices, correct?</p> <p>24 A. I would assume so.</p> <p>25 Q. Okay. And so one way to figure out the</p>	<p>1 A. According to the records, yes.</p> <p>2 Q. You didn't do any work for Ethicon prior</p> <p>3 to 2003?</p> <p>4 A. Not to my recollection.</p> <p>5 Q. Okay. And if Ethicon has records that</p> <p>6 indicate you did work for them prior to 2003, would</p> <p>7 you disagree with those records?</p> <p>8 A. I would have no reason to disagree.</p> <p>9 Q. Okay. And between the -- did you do any</p> <p>10 work for Ethicon in 2013?</p> <p>11 A. I don't -- I don't recall, but I don't</p> <p>12 believe so.</p> <p>13 Q. Okay. But according to your accountant,</p> <p>14 there is no records of any payments from Ethicon to</p> <p>15 you in 2013?</p> <p>16 A. According to my accountant.</p> <p>17 Q. Okay. How about 2014?</p> <p>18 A. No. Same -- same story.</p> <p>19 Q. Same story. No payments from Ethicon to</p> <p>20 you, according to your accountant, in 2014?</p> <p>21 A. According to my accountant.</p> <p>22 Q. How about 2015?</p> <p>23 A. Same story.</p> <p>24 Q. Same story?</p> <p>25 A. (Nodding head up and down.)</p>
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<p>1 exact total of payments by year would be to ask</p> <p>2 Ethicon for those invoices that you submitted to</p> <p>3 them?</p> <p>4 A. If they have them, yes.</p> <p>5 Q. Okay. If they have them, that would be a</p> <p>6 good way of totaling up the payments?</p> <p>7 A. If they have them.</p> <p>8 Q. Okay. How did you go about totaling the</p> <p>9 payments when you didn't have a 1099?</p> <p>10 A. At the time I had a 1099. The -- I</p> <p>11 submitted it to my accountant. He submitted it for</p> <p>12 his taxes. And, unfortunately, I don't know what he</p> <p>13 did with the 1099.</p> <p>14 Q. But the information is based on what you</p> <p>15 believe is from a 1099 that no longer is in your</p> <p>16 possession or you're able to get?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Did you ask the IRS to send you</p> <p>19 copies of these 1099s?</p> <p>20 MR. MORIARTY: Objection.</p> <p>21 THE WITNESS: No.</p> <p>22 BY MR. JONES:</p> <p>23 Q. Just roughly, it looks like the first year</p> <p>24 you acted as a consultant for Ethicon was in 2003,</p> <p>25 correct?</p>	<p>1 Q. Okay. I take it that you anticipate</p> <p>2 payments from Ethicon in 2016 related to litigation</p> <p>3 consulting work?</p> <p>4 A. Does Ethicon pay me?</p> <p>5 Q. Do you know one way or the other whether</p> <p>6 you anticipate payments from Ethicon for your</p> <p>7 litigation consulting work in 2016?</p> <p>8 A. Ultimately, if Ethicon is the one that</p> <p>9 pays through the lawyers' office, yes.</p> <p>10 Q. Okay.</p> <p>11 A. I don't know whether it goes from -- comes</p> <p>12 from the lawyer or straight from Ethicon. I don't</p> <p>13 know.</p> <p>14 Q. Have you totaled the amount of payments,</p> <p>15 starting in 2003 and ending in 2012, from Ethicon to</p> <p>16 you in your role as a consultant?</p> <p>17 A. No. I just got you the sheet.</p> <p>18 Q. Okay. It looks like, a rough estimate,</p> <p>19 it's going to be around a half a million dollars. Is</p> <p>20 that fair?</p> <p>21 A. If that's what the sheet says.</p> <p>22 Q. Okay. We'll add it up over break, get an</p> <p>23 exact number.</p> <p>24 A. Sure. Okay.</p> <p>25 Q. So it's fair to say from the year --</p>

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<p>1 strike that.</p> <p>2 It's fair to say, starting in the year</p> <p>3 2003 through the year 2012, you had a relationship</p> <p>4 with Ethicon as a consultant physician, correct?</p> <p>5 A. Yes.</p> <p>6 Q. And it's fair to say from -- starting in</p> <p>7 the year 2003 through the year 2012, for each of</p> <p>8 those years, you received payments from Ethicon for</p> <p>9 your role as a consultant physician, correct?</p> <p>10 A. Correct.</p> <p>11 Q. It's fair to say, between the years 2003</p> <p>12 to 2012, every single one of those years, you</p> <p>13 performed work for Ethicon as a consultant physician,</p> <p>14 correct?</p> <p>15 A. Correct.</p> <p>16 Q. It's fair to say before you agreed to be a</p> <p>17 litigation consultant for Ethicon, you had a ten-year</p> <p>18 relationship with Ethicon in your role as a</p> <p>19 consultant physician, correct?</p> <p>20 A. 2003 till when?</p> <p>21 Q. To the end of 2012.</p> <p>22 A. Yes.</p> <p>23 Q. Do you know how many days -- have you</p> <p>24 tracked -- strike that.</p> <p>25 Have you tracked at all how many days out</p>	<p>1 products?</p> <p>2 MR. MORIARTY: Objection.</p> <p>3 THE WITNESS: How are you defining</p> <p>4 "promotion"?</p> <p>5 BY MR. JONES:</p> <p>6 Q. We'll say -- how would you define it?</p> <p>7 A. Well, if you're saying that I'm endorsing</p> <p>8 Ethicon products, I did not. But that's -- I mean,</p> <p>9 that's what I take from "promotion."</p> <p>10 Q. I will -- let's agree that endorsing the</p> <p>11 products is not included at all in my question when I</p> <p>12 use the word "promote."</p> <p>13 A. Okay. You just asked me.</p> <p>14 Q. Okay. So having -- now knowing that, is</p> <p>15 it fair to say, within the years 2003 to 2012 in your</p> <p>16 role as a consultant for Ethicon, at some point your</p> <p>17 role included promoting the use of Ethicon products?</p> <p>18 MR. MORIARTY: Objection. Form.</p> <p>19 THE WITNESS: Well, again, we struck only</p> <p>20 one definition of "promotion." So I can't state</p> <p>21 until you actually define it for me in a</p> <p>22 positive manner what "promotion" means, not in</p> <p>23 an absence of one thing.</p> <p>24 BY MR. JONES:</p> <p>25 Q. Okay. How about we define it just by the</p>
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<p>1 of the year on average you do consultant work for</p> <p>2 Ethicon?</p> <p>3 A. No.</p> <p>4 Q. You don't know one way or the other how</p> <p>5 many days in the calendar year 2010 you spent</p> <p>6 consulting with Ethicon?</p> <p>7 A. No.</p> <p>8 Q. If someone, perhaps a juror, wanted to</p> <p>9 know how many calendar days you spent in 2010</p> <p>10 consulting with Ethicon, would there be a way for</p> <p>11 them to find that information out?</p> <p>12 MR. MORIARTY: Objection. Go ahead.</p> <p>13 THE WITNESS: I wouldn't know.</p> <p>14 BY MR. JONES:</p> <p>15 Q. Okay. So that's not information you have</p> <p>16 at access?</p> <p>17 A. No.</p> <p>18 Q. Is it fair to say that, in your consulting</p> <p>19 work between the years 2003 and 2012 for Ethicon,</p> <p>20 some of the events you conducted for Ethicon were</p> <p>21 marketing events?</p> <p>22 A. Yes.</p> <p>23 Q. Is it fair to say that, between the years</p> <p>24 2003 and 2012 in your consulting work for Ethicon,</p> <p>25 some of your work involved the promotion of Ethicon</p>	<p>1 dictionary, how it defines it. Does that work for</p> <p>2 you?</p> <p>3 A. I'm okay with that. Sure.</p> <p>4 Q. Okay. I'll ask the same question again</p> <p>5 using the dictionary meaning of "promote."</p> <p>6 A. Thank you.</p> <p>7 Q. Okay. Is it fair to say, within 2003 to</p> <p>8 2012 in your role as a consultant for Ethicon, at</p> <p>9 some point in time your role as a consultant for</p> <p>10 Ethicon included promoting the use of Ethicon</p> <p>11 products?</p> <p>12 MR. MORIARTY: Objection.</p> <p>13 THE WITNESS: What's the dictionary</p> <p>14 definition?</p> <p>15 BY MR. JONES:</p> <p>16 Q. "Further the progress of, support or</p> <p>17 actively encourage."</p> <p>18 A. "Actively encourage" I would take issue</p> <p>19 with.</p> <p>20 Q. Okay. Between the years 2003 to 2012 in</p> <p>21 your role as a consultant for Ethicon, you never</p> <p>22 actively encouraged the use of Ethicon products?</p> <p>23 A. No.</p> <p>24 Q. Okay. Between the years -- strike that.</p> <p>25 Did you ever work as a consultant for any</p>

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<p>1 other mesh companies?</p> <p>2 A. No.</p> <p>3 Q. So from the years starting in the year</p> <p>4 2003 all the way up to today, March 16th, 2016,</p> <p>5 you've never acted as a consultant physician for any</p> <p>6 mesh company other than Ethicon, correct?</p> <p>7 A. What was the time frame again?</p> <p>8 Q. Any time frame. It was 2003 to today.</p> <p>9 A. That I haven't -- I'm sorry. The</p> <p>10 negatives are getting me.</p> <p>11 Q. How about this? Have you ever acted as a</p> <p>12 consultant for any other mesh company besides</p> <p>13 Ethicon?</p> <p>14 A. No.</p> <p>15 Q. All right. It's fair to say that the only</p> <p>16 mesh company you've ever consulted for is Ethicon?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Have you -- do you currently have</p> <p>19 any consulting relationships with any companies?</p> <p>20 A. Any companies?</p> <p>21 Q. Any companies.</p> <p>22 A. Yes.</p> <p>23 Q. Can you name those companies for us?</p> <p>24 A. I believe the one company currently I have</p> <p>25 a consulting relationship with is Astellas</p>	<p>1 Q. It's not that important.</p> <p>2 A. Okay.</p> <p>3 Q. Astellas, where are they located?</p> <p>4 A. I don't know. They move around a lot.</p> <p>5 Q. Do they -- how did you get involved with</p> <p>6 Astellas?</p> <p>7 A. I see patients that -- I see patients with</p> <p>8 the condition that their product is designed to</p> <p>9 treat.</p> <p>10 Q. Okay. Did they contact you or did you</p> <p>11 contact them?</p> <p>12 A. They contacted me.</p> <p>13 Q. And I assume you signed -- you're under --</p> <p>14 you signed an agreement or contract with Astellas to</p> <p>15 be a consultant for them?</p> <p>16 A. I did.</p> <p>17 Q. Part of your role as a consultant for</p> <p>18 Astellas, you go out and you speak about a product</p> <p>19 that they market, correct?</p> <p>20 A. I speak more on the condition that their</p> <p>21 product treats.</p> <p>22 Q. In your role as a consultant for Astellas,</p> <p>23 when you go out and you do these speaking</p> <p>24 engagements, what is your hourly rate?</p> <p>25 A. I don't know.</p>
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<p>1 Pharmaceuticals.</p> <p>2 Q. What's the nature of that consulting role?</p> <p>3 What are you doing for Astellas?</p> <p>4 MR. MORIARTY: Objection. If there's a</p> <p>5 secrecy agreement you have to --</p> <p>6 THE WITNESS: Oh, I appreciate that.</p> <p>7 Thank you.</p> <p>8 MR. MORIARTY: -- give it the vaguest --</p> <p>9 give him the vaguest description.</p> <p>10 THE WITNESS: I speak for them. Leave it</p> <p>11 at that.</p> <p>12 BY MR. JONES:</p> <p>13 Q. Okay. Can you tell us what product -- how</p> <p>14 about this? Strike that.</p> <p>15 Is there a certain product that's the</p> <p>16 focus of your consulting role with this company?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Can you tell us the product? I</p> <p>19 don't want you to get in any trouble with any secrecy</p> <p>20 agreements, confidentiality stuff, but having said</p> <p>21 that, if you're out speaking about it.</p> <p>22 A. I don't know that I will get in trouble</p> <p>23 with anybody. Having said that, I don't know.</p> <p>24 Q. Don't --</p> <p>25 A. Don't go there. Okay.</p>	<p>1 Q. Okay. It's fair to say Astellas is paying</p> <p>2 you in your role as a consultant for them?</p> <p>3 A. Yes, sir.</p> <p>4 Q. Okay. You don't know, as you sit here</p> <p>5 today, what -- what that rate is, but you do know</p> <p>6 they're paying you money?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. Any other companies that you're</p> <p>9 currently acting as a consultant physician for?</p> <p>10 A. No.</p> <p>11 Q. Okay. So we have Astellas; we have</p> <p>12 Ethicon. Any other companies besides Astellas and</p> <p>13 Ethicon that you've acted as a consultant for over</p> <p>14 the course of your career as a doctor?</p> <p>15 A. Yes.</p> <p>16 Q. What companies?</p> <p>17 A. Pfizer. Ortho-McNeil. Watson</p> <p>18 Pharmaceuticals. I'm sure I'm leaving some out, but</p> <p>19 it's been a long time.</p> <p>20 Q. As you sit here today, you recall that the</p> <p>21 names of companies including Astellas, Ethicon,</p> <p>22 Pfizer, Watson Pharmaceuticals, and Ortho-McNeil as</p> <p>23 companies you've acted as a consultant for in your</p> <p>24 career as a doctor?</p> <p>25 A. Yes.</p>

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<p>1 Q. There may be others that you just don't 2 recall today?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. What type of work do you do for 5 Pfizer?</p> <p>6 A. Again, at the risk of not -- well, 7 currently, I don't do any work for Pfizer.</p> <p>8 Q. What type of work did you do for Pfizer?</p> <p>9 A. I was a speaker.</p> <p>10 Q. When you were a consultant for Pfizer, you 11 would be paid money for speaking engagements, 12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. As you sit here today, do you recall how 15 much Pfizer paid you for your work as a consultant?</p> <p>16 A. No.</p> <p>17 Q. I'm going to ask the same questions for 18 the other companies, exact same questions.</p> <p>19 A. Okay.</p> <p>20 Q. Is it fair to say in your role as a 21 consultant for Ortho-McNeil you did speaking 22 engagements which Ortho-McNeil paid you money for?</p> <p>23 A. Yes.</p> <p>24 Q. As you sit here today, you don't know how 25 much Ortho-McNeil paid you in your role as a</p>	<p>1 A. I -- yes.</p> <p>2 Q. Have you acted as a consultant with the 3 company that markets InterStim?</p> <p>4 A. I don't remember.</p> <p>5 Q. You think if you asked your accountant 6 what companies you've acted as a consultant for over 7 the course of your medical career and been paid by 8 those companies in your role as consultant, they 9 would have, he or she, would have an answer for you?</p> <p>10 MR. MORIARTY: Objection.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. JONES:</p> <p>13 Q. Okay. Move on to Exhibit 6, which you 14 kindly brought with you today, which there's only one 15 copy so we'll look at it together. It's titled 16 "Invoice for Consulting Services," correct?</p> <p>17 A. Yes.</p> <p>18 (Carbone 6 was marked for identification.)</p> <p>19 BY MR. JONES:</p> <p>20 Q. It's fair to say Exhibit 6 represents the 21 invoices you've billed for your work as your role as 22 a litigation consultant for Ethicon, correct?</p> <p>23 A. Again, I was under the understanding I was 24 working for the drug legal firm. But I guess if I'm 25 working for Ethicon, as you say, then yes.</p>
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<p>1 consultant, correct?</p> <p>2 A. No.</p> <p>3 Q. Correct that in your role as a consultant 4 for Watson Pharmaceutical, you did speaking 5 engagements which Watson Pharmaceutical paid you 6 money for, correct?</p> <p>7 A. Correct.</p> <p>8 Q. As you sit here today, you just don't 9 recall how much Watson Pharmaceutical paid you for 10 your role as a consultant for them, correct?</p> <p>11 A. Correct.</p> <p>12 Q. Have you ever acted as a consultant for 13 Medtronic?</p> <p>14 A. Yes.</p> <p>15 Q. What do you do for Medtronic or what did 16 you do for Medtronic?</p> <p>17 A. I apologize. I withdraw that. No, I was 18 not a consultant.</p> <p>19 Q. Okay.</p> <p>20 A. I apologize.</p> <p>21 Q. You've never acted as a consultant 22 physician for the company Medtronic over your course 23 of your medical career, correct?</p> <p>24 A. Not that I recall.</p> <p>25 Q. Do you do any work with InterStim device?</p>	<p>1 Q. Is it fair that Exhibit 6 represents 2 invoices that you've billed for your litigation 3 consulting work in this transvaginal mesh litigation? 4 These are the invoices for your expert consulting 5 work, correct?</p> <p>6 A. Yeah.</p> <p>7 Q. Okay. But for the missing Prolift invoice 8 that we're going to get and add to Exhibit 6, 9 correct?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. Have you totaled these up?</p> <p>12 A. Nope.</p> <p>13 Q. Okay. We'll do that on break.</p> <p>14 How many total hours have you spent in 15 your role as a litigation consultant for Ethicon?</p> <p>16 A. That's an interesting question. How many 17 hours have I spent reviewing all the materials or how 18 many hours have I billed?</p> <p>19 Q. Both.</p> <p>20 A. I spent a lot more hours reviewing the 21 materials than what I billed.</p> <p>22 Q. Okay. How many?</p> <p>23 A. A lot.</p> <p>24 Q. A lot?</p> <p>25 A. A lot.</p>

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<p>1 Q. More than what you billed for?</p> <p>2 A. Yeah.</p> <p>3 Q. So if we look at the invoices, we total</p> <p>4 up all the hours, including with the missing invoice</p> <p>5 that wasn't brought today, we'll know the total</p> <p>6 amount of hours you've billed, correct?</p> <p>7 A. We'll know the total amount of hours that</p> <p>8 I've billed, yes.</p> <p>9 Q. And then you're saying that you spent more</p> <p>10 working on the case above and beyond the hours that</p> <p>11 you've actually billed, correct?</p> <p>12 A. Oh, yes.</p> <p>13 Q. Okay. And if we double the amount of</p> <p>14 hours that you billed?</p> <p>15 MR. MORIARTY: Objection.</p> <p>16 BY MR. JONES:</p> <p>17 Q. I just want a general idea of the total</p> <p>18 amount of time you spent on the case.</p> <p>19 A. When I reviewed these articles -- I've</p> <p>20 been reviewing this material since I was introduced</p> <p>21 to the mesh in 1998. So the body of my professional</p> <p>22 career was spent reviewing these materials. And in</p> <p>23 that way, I've been reviewing these materials for</p> <p>24 over 20 years.</p> <p>25 Q. Okay.</p>	<p>1 related to the topics in your report that you've</p> <p>2 written, correct?</p> <p>3 A. Off and on, yes.</p> <p>4 Q. And do you continue to keep up to date</p> <p>5 with the medical literature on these subjects?</p> <p>6 A. I try.</p> <p>7 Q. You try?</p> <p>8 A. (Nodding head up and down.)</p> <p>9 Q. When's the last time you did a literature</p> <p>10 review?</p> <p>11 A. Read an article?</p> <p>12 Q. Sure.</p> <p>13 A. I read an article last week.</p> <p>14 Q. Okay. What article was that?</p> <p>15 A. There was an article -- well, last week I</p> <p>16 reviewed the article, the Schimph article.</p> <p>17 Q. Okay. How did you find that article?</p> <p>18 A. I reviewed it -- well, I had reviewed it</p> <p>19 in the past in my general reading, and then I</p> <p>20 reviewed in preparation for this litigation.</p> <p>21 Q. Was that article sent to you by Ethicon?</p> <p>22 A. Originally, no.</p> <p>23 Q. Eventually, Ethicon sent you that article,</p> <p>24 though?</p> <p>25 A. Eventually it was in the materials that</p>
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<p>1 A. So I would submit that I spent a career of</p> <p>2 preparing to answer the questions you may ask me.</p> <p>3 Q. Okay. You've spent close to 20 years</p> <p>4 reviewing materials in support of your opinions in</p> <p>5 this litigation?</p> <p>6 MR. MORIARTY: Objection. Form.</p> <p>7 Go ahead.</p> <p>8 THE WITNESS: Not continuously.</p> <p>9 BY MR. JONES:</p> <p>10 Q. Okay. For the past 20 years off and on,</p> <p>11 you've reviewed -- you have reviewed materials that</p> <p>12 support your opinions in this litigation?</p> <p>13 A. I've read. I've gone to CME. I've talked</p> <p>14 with other clinicians. I've presented. I've been</p> <p>15 involved in -- I've operated. My knowledge, my</p> <p>16 training, my experience, my review of the literature,</p> <p>17 my interaction with other colleagues, all that is the</p> <p>18 sum of what has gone into, and more -- I'm sure I'm</p> <p>19 not touching on everything -- is the sum of what I</p> <p>20 drew upon, if you will, to determine my opinions.</p> <p>21 Q. Okay. And does that include review of the</p> <p>22 medical literature?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. So over the course of the past 20</p> <p>25 years off and on, you've reviewed medical literature</p>	<p>1 they sent to me, yes.</p> <p>2 Q. Okay. When's the last time you read an</p> <p>3 article that Ethicon didn't give you?</p> <p>4 MR. MORIARTY: Objection.</p> <p>5 THE WITNESS: I read an article -- I</p> <p>6 probably read an article, again, last week.</p> <p>7 BY MR. JONES:</p> <p>8 Q. Okay. What article was that?</p> <p>9 A. I don't remember.</p> <p>10 Q. You don't remember the article you read</p> <p>11 last week?</p> <p>12 A. I don't remember the article I read last</p> <p>13 week.</p> <p>14 Q. So it's fair to say that, when you're</p> <p>15 keeping up to date with the literature, just because</p> <p>16 you read an article last week doesn't mean that</p> <p>17 you're going to recall it on the spot the next week,</p> <p>18 correct?</p> <p>19 A. Repeat your question?</p> <p>20 Q. Sure. You read an article last week.</p> <p>21 A. Okay.</p> <p>22 Q. You don't recall what the title of the</p> <p>23 article was today, correct?</p> <p>24 A. I don't recall what the title of the</p> <p>25 article was today, no.</p>

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<p>1 Q. Do you recall what the subject matter of</p> <p>2 the article was?</p> <p>3 A. The subject matter was urodynamics.</p> <p>4 Q. Okay. Do you recall the conclusion?</p> <p>5 A. The conclusion was something about --</p> <p>6 something about patients' anxiety in the setting and</p> <p>7 affecting the outcomes.</p> <p>8 Q. Okay. Did you read any other articles,</p> <p>9 besides that one article last week, that Ethicon did</p> <p>10 not provide you?</p> <p>11 MR. MORIARTY: Objection.</p> <p>12 THE WITNESS: I don't remember.</p> <p>13 BY MR. JONES:</p> <p>14 Q. Okay. Do you -- what's your normal</p> <p>15 customary practice in reviewing medical literature?</p> <p>16 A. I received -- I receive journals from</p> <p>17 Neurourology and Urodynamics. I receive journals</p> <p>18 from the Journal of Urology. I receive the Gold</p> <p>19 Journal. I receive some Clinical Review,</p> <p>20 Contemporary Review, some AUA News, some AUA Updates.</p> <p>21 And I review them from time to time.</p> <p>22 Q. Okay. So it's fair to say that the</p> <p>23 journals and newsletters you just listed are ones</p> <p>24 that you regularly receive?</p> <p>25 A. Yes.</p>	<p>1 A. Well, what do you mean by "methodology"?</p> <p>2 Q. Based on the authors of the articles. Is</p> <p>3 that one thing you take into account?</p> <p>4 A. No, not necessarily.</p> <p>5 Q. Okay. Do you take into account the</p> <p>6 conflict of interest of the articles, of the authors</p> <p>7 in the articles?</p> <p>8 A. Not necessarily.</p> <p>9 Q. Okay. Do you -- when you read a journal</p> <p>10 article, do you take note whether the authors have a</p> <p>11 conflict of interest or not?</p> <p>12 A. Not necessarily.</p> <p>13 Q. Okay. Why not?</p> <p>14 A. I'm looking for articles that adhere to</p> <p>15 the highest scientific rigor. I think it's</p> <p>16 considered Level 1 evidence, randomized control</p> <p>17 trials. You know, again, the design -- not</p> <p>18 necessarily the methodology, but the design of the</p> <p>19 study is paramount.</p> <p>20 Q. So if you're looking at a journal article,</p> <p>21 the number one thing you're looking at is the design</p> <p>22 of the underlying trial or study that's being</p> <p>23 reported in that article?</p> <p>24 A. Rephrase that? Restate that again?</p> <p>25 Q. Sure. The primary issue you're looking at</p>
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<p>1 Q. Okay. And you may not read them all, but</p> <p>2 you try to keep up to date on those journals?</p> <p>3 A. As best I can.</p> <p>4 Q. Okay. And you consider all of those</p> <p>5 journals a reasonable authority in your field?</p> <p>6 MR. MORIARTY: Objection. Form.</p> <p>7 Go ahead.</p> <p>8 THE WITNESS: More some than others.</p> <p>9 BY MR. JONES:</p> <p>10 Q. Which ones more so than others?</p> <p>11 A. I feel that Neurourology and Urodynamics</p> <p>12 is one that I feel is authoritative, the Journal of</p> <p>13 Urology, the Gold Journal. Some of the other ones,</p> <p>14 some of the review ones, maybe not so much --</p> <p>15 Q. Okay.</p> <p>16 A. -- depending on the level of evidence that</p> <p>17 they present and the articles that they accept.</p> <p>18 Q. Sure, sure. Meaning not all peer-reviewed</p> <p>19 journal articles are created equal?</p> <p>20 A. Correct.</p> <p>21 Q. Okay. Some you might give more weight to</p> <p>22 than others?</p> <p>23 A. Correct.</p> <p>24 Q. Based on the methodology used in the</p> <p>25 article, correct?</p>	<p>1 when you review a journal article is the design of</p> <p>2 the study or trial reported in the article?</p> <p>3 A. The primary -- it's not the sole, but it's</p> <p>4 the primary.</p> <p>5 Q. So yes?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Randomized control trials are</p> <p>8 Level 1 type of evidence, correct?</p> <p>9 A. Yes.</p> <p>10 Q. Randomized control trials are the highest</p> <p>11 level of evidence, correct?</p> <p>12 A. We now have systematic reviews that fit</p> <p>13 into the highest level -- Level 1 evidence. So it's</p> <p>14 a matter of -- well, they're Level 1 evidence. Let's</p> <p>15 leave it at that.</p> <p>16 Q. Okay. When you review a journal article</p> <p>17 and you do happen to take note that one of the</p> <p>18 authors has a conflict of interest, does that factor</p> <p>19 in of how you view the conclusions of the article?</p> <p>20 MR. MORIARTY: Objection.</p> <p>21 THE WITNESS: If it is a well-designed</p> <p>22 Level 1 study, then no.</p> <p>23 BY MR. JONES:</p> <p>24 Q. If the journal article is reporting on a</p> <p>25 study that is not Level 1 evidence and the author has</p>

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<p style="text-align: right;">Page 34</p> <p>1 a conflict of interest, how does that factor into how</p> <p>2 you view the conclusions in the article?</p> <p>3 MR. MORIARTY: Objection. Form.</p> <p>4 Go ahead.</p> <p>5 THE WITNESS: Repeat the question.</p> <p>6 BY MR. JONES:</p> <p>7 Q. Sure.</p> <p>8 A. Because I want to make sure I answer it</p> <p>9 specifically for you.</p> <p>10 Q. Sure. When the article reports on a study</p> <p>11 or trial that is not Level 1 evidence and one of the</p> <p>12 authors has a conflict of interest, how does that</p> <p>13 factor into how you view the conclusions in the</p> <p>14 article?</p> <p>15 MR. MORIARTY: Objection. Form.</p> <p>16 Go ahead.</p> <p>17 THE WITNESS: I view the study as a</p> <p>18 non-Level 1 study. So I guess my best answer</p> <p>19 for you is studies don't exist in a vacuum. And</p> <p>20 regardless of the author, you got to compare a</p> <p>21 level -- a low-level study -- this is called</p> <p>22 low-level study -- to a high-level study</p> <p>23 regardless of the author, regardless of their</p> <p>24 relationship, and just look at the methodology,</p> <p>25 the conclusions, and is it a Level 4 study? If</p>	<p style="text-align: right;">Page 36</p> <p>1 holding themselves out as an expert in this</p> <p>2 litigation?</p> <p>3 A. Well, it means that I don't put as much</p> <p>4 weight in a Level 4 study, or a low-level study, than</p> <p>5 I do a high-level study.</p> <p>6 Q. Is -- are studies that are not, as you</p> <p>7 call them, Level 1 evidence low-level studies?</p> <p>8 A. I'm sorry?</p> <p>9 Q. Are studies that are not Level 1 evidence</p> <p>10 low-level quality of studies?</p> <p>11 MR. MORIARTY: Objection.</p> <p>12 THE WITNESS: Well, it's a spectrum. So I</p> <p>13 can't -- you know, it's not a dichotomy. So I</p> <p>14 would say lower.</p> <p>15 BY MR. JONES:</p> <p>16 Q. Okay. Are you familiar with the concept</p> <p>17 of milestone payments?</p> <p>18 A. I'm sorry?</p> <p>19 Q. Are you familiar with the concept</p> <p>20 milestone payments in the context of study -- studies</p> <p>21 and trials and analyzing data?</p> <p>22 A. No, I'm not familiar with that.</p> <p>23 Q. You've never heard the term "milestone</p> <p>24 payment"?</p> <p>25 A. I have not.</p>
<p style="text-align: right;">Page 35</p> <p>1 it's a level 4 study, you don't weight it as</p> <p>2 high as a Level 1 study. And, you know, the</p> <p>3 method -- the method is the key.</p> <p>4 So I don't know how to answer your</p> <p>5 question.</p> <p>6 BY MR. JONES:</p> <p>7 Q. Do -- is it fair to say that when you</p> <p>8 review a journal article, you do note whether the</p> <p>9 authors have a conflict of interest or not?</p> <p>10 MR. MORIARTY: Objection. Form.</p> <p>11 Go ahead.</p> <p>12 THE WITNESS: It's written there. Yeah, I</p> <p>13 read it.</p> <p>14 BY MR. JONES:</p> <p>15 Q. Past that, it doesn't factor in at all?</p> <p>16 A. I guess I got to answer the same way.</p> <p>17 Past that, I got to look at the data and the method</p> <p>18 by which the data has been analyzed.</p> <p>19 Q. Okay. Brings up a good point. Is it</p> <p>20 important to know how the data's been analyzed when</p> <p>21 you review a journal article?</p> <p>22 A. That it conforms to a Level 1 standard,</p> <p>23 that's what I want to know.</p> <p>24 Q. If it hasn't conformed to a Level 1</p> <p>25 standard, what does that mean to you as a -- someone</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. I want to turn back to your reliance list,</p> <p>2 go over some specific things that you've listed on</p> <p>3 your reliance list. I want you to turn to the very</p> <p>4 last page.</p> <p>5 A. I don't have a copy of it.</p> <p>6 Q. Sorry. Your attorney stole it from you.</p> <p>7 Last page titled "Expert Reports."</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And you've listed one, two, three,</p> <p>10 four, five, six, seven, eight, nine, ten, 11, 12, 13,</p> <p>11 14, 15, 16, 17 expert reports from plaintiff experts</p> <p>12 that you've reviewed, correct?</p> <p>13 A. Yes, sir.</p> <p>14 Q. And did you review all of those?</p> <p>15 A. At one point or another, I did.</p> <p>16 Q. Okay. And you read them from start to</p> <p>17 finish?</p> <p>18 A. At one point or another I did.</p> <p>19 Q. Okay. And did you review -- you</p> <p>20 understand that those reports have reliance lists as</p> <p>21 well, like yours, as well?</p> <p>22 A. I imagine they do.</p> <p>23 Q. And did you review all of the reliance</p> <p>24 materials on their reliance list as well as the</p> <p>25 reports?</p>

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<p>1 A. No.</p> <p>2 Q. Okay. So when you reviewed these expert</p> <p>3 reports, you just read the report; you didn't review</p> <p>4 the underlying reliance materials that they</p> <p>5 submitted. Correct?</p> <p>6 A. Correct.</p> <p>7 Q. Okay. How long did it take you to review</p> <p>8 these 17 expert reports? Estimate.</p> <p>9 A. Couple of days.</p> <p>10 Q. Couple days?</p> <p>11 A. Yeah.</p> <p>12 Q. So the guesstimate is 16 hours?</p> <p>13 A. Over a period of days, yeah.</p> <p>14 Q. Okay. So roughly speaking, 16 hours to</p> <p>15 review these 18 reports?</p> <p>16 A. I'd say probably about 18 to 20 if you</p> <p>17 give an hour a report, yeah.</p> <p>18 Q. How about 15 to 20 hours? Is that fair?</p> <p>19 A. Fair enough.</p> <p>20 Q. Okay. 15 to 20 hours reviewing these 18</p> <p>21 plaintiff expert reports, correct?</p> <p>22 A. Correct.</p> <p>23 Q. How much time did you spend drafting your</p> <p>24 report, your TVT report?</p> <p>25 A. Drafting, I believe --</p>	<p>1 Q. And you drafted a report in each of those</p> <p>2 five cases specific to those plaintiffs, correct?</p> <p>3 MR. MORIARTY: Objection. Objection.</p> <p>4 THE WITNESS: Repeat it again?</p> <p>5 BY MR. JONES:</p> <p>6 Q. For each of those five cases, you wrote a</p> <p>7 report, correct?</p> <p>8 MR. MORIARTY: Objection.</p> <p>9 BY MR. JONES:</p> <p>10 Q. Where you reviewed their medical records?</p> <p>11 A. Yeah.</p> <p>12 Q. You wrote a case-specific report in each</p> <p>13 of those five cases?</p> <p>14 MR. MORIARTY: Objection.</p> <p>15 BY MR. JONES:</p> <p>16 Q. Yes?</p> <p>17 A. Yes.</p> <p>18 Q. Yes. Okay. How much time did you spend</p> <p>19 writing those five case-specific reports?</p> <p>20 A. Less time than the --</p> <p>21 MR. MORIARTY: Do you want him to look at</p> <p>22 the invoices or just give it off the top of his</p> <p>23 head?</p> <p>24 THE WITNESS: Two or three hours.</p> <p>25 BY MR. JONES:</p>
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<p>1 MR. MORIARTY: Exhibit --</p> <p>2 MR. JONES: The invoices?</p> <p>3 MR. MORIARTY: 6.</p> <p>4 BY MR. JONES:</p> <p>5 Q. You got an answer for me?</p> <p>6 A. I think around five hours.</p> <p>7 Q. Five hours drafting the TVT report. How</p> <p>8 many hours drafting Prolift report? Keep in mind,</p> <p>9 Doctor, that's just what you billed for, not what you</p> <p>10 actually did.</p> <p>11 A. Right.</p> <p>12 Q. So don't short-change yourself.</p> <p>13 A. I probably say about the same.</p> <p>14 Q. Okay. Five hours for your Prolift report.</p> <p>15 How much time for -- how many case-specific reports</p> <p>16 have you drafted?</p> <p>17 A. Five.</p> <p>18 Q. Five? Did Ethicon ask you to work on any</p> <p>19 other cases besides those five?</p> <p>20 A. No.</p> <p>21 Q. So Ethicon only asked you to work on five</p> <p>22 cases, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And you agreed to work on five cases?</p> <p>25 A. Correct.</p>	<p>1 Q. Two or three hours?</p> <p>2 A. Not as much as the general reports.</p> <p>3 Q. Okay. For those five. Okay. How much</p> <p>4 time reviewing the materials that Ethicon sent you?</p> <p>5 A. Including these?</p> <p>6 Q. Everything. Everything Ethicon sent you.</p> <p>7 We're taking out the -- the time that you spent</p> <p>8 reviewing the expert reports, we're taking out the</p> <p>9 time you spent drafting your TVT report, your Prolift</p> <p>10 report, and your case-specific reports.</p> <p>11 A. Wait, wait. What are we taking out?</p> <p>12 Q. Okay. We're --</p> <p>13 A. I'm just trying to --</p> <p>14 Q. Yeah. I know.</p> <p>15 A. It's a lot of math here.</p> <p>16 Q. I know. I told you. I warned you at the</p> <p>17 beginning I was going to do a horrible job.</p> <p>18 A. All right. I'm with you.</p> <p>19 Q. So we've got nailed down 15 to 20 hours</p> <p>20 reviewing expert reports of plaintiff experts. Okay?</p> <p>21 A. Which were part of the --</p> <p>22 Q. Your big review.</p> <p>23 A. Well, in addition to some of the case</p> <p>24 reports.</p> <p>25 Q. Okay.</p>

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<p>1 A. That was included in some of the review of</p> <p>2 case reports.</p> <p>3 Q. Okay.</p> <p>4 A. Okay. I'm with you. So 16 is there.</p> <p>5 Q. All right.</p> <p>6 A. Keep going.</p> <p>7 Q. Everything else that Ethicon sent you, how</p> <p>8 much time did you spend reviewing that?</p> <p>9 A. Well, it's hard to say because a lot of</p> <p>10 the articles I had seen before. So not a vast amount</p> <p>11 of time. I don't know. Those materials back there,</p> <p>12 I was able to go through relatively quickly. I'd say</p> <p>13 three or four hours looking through them, with the</p> <p>14 understanding that a lot of them I had already seen.</p> <p>15 Q. Okay. And you're talking about medical</p> <p>16 literature primarily?</p> <p>17 A. That was all medical literature.</p> <p>18 Q. All medical literature. Did you review</p> <p>19 any internal Ethicon documents?</p> <p>20 A. Some of it is.</p> <p>21 Q. Some?</p> <p>22 A. Yeah.</p> <p>23 Q. Okay. How many?</p> <p>24 A. Not -- a minority.</p> <p>25 Q. Very small amount of internal Ethicon</p>	<p>1 Q. But not the internal Ethicon corporate</p> <p>2 documents?</p> <p>3 A. No.</p> <p>4 Q. Okay. Do you know -- did you review any</p> <p>5 internal Ethicon design documents?</p> <p>6 A. I'm sure I may have or may have not. I</p> <p>7 don't recall specific Ethicon -- what did you say?</p> <p>8 Q. How about, did you review the design</p> <p>9 specifications for any of the products that we're</p> <p>10 discussing here today?</p> <p>11 A. I don't remember specifically.</p> <p>12 Q. As you sit here today, you don't have any</p> <p>13 recollection reviewing the design specifications for</p> <p>14 the TVT line of products for the Prolift, correct?</p> <p>15 A. I do not have any specific recollection of</p> <p>16 those things.</p> <p>17 Q. Do you know what a -- do you know what --</p> <p>18 who the company MedScan is?</p> <p>19 A. MedScan? No.</p> <p>20 Q. Do you know who Provincia is?</p> <p>21 A. No.</p> <p>22 Q. Do you know what an FMEA is?</p> <p>23 A. FEMA?</p> <p>24 Q. FMEA.</p> <p>25 A. Oh, FMEA. No.</p>
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<p>1 articles for you to review?</p> <p>2 A. A minority. How do you define "very</p> <p>3 small," right?</p> <p>4 Q. Did you review more than 100 internal</p> <p>5 documents?</p> <p>6 A. No.</p> <p>7 Q. Did you review more than 50?</p> <p>8 A. I don't think so.</p> <p>9 Q. Okay. If you want -- I think I've looked</p> <p>10 at your reliance list. There's about 10 --</p> <p>11 A. Yeah.</p> <p>12 Q. -- 10 --</p> <p>13 A. Yeah.</p> <p>14 Q. So 10 or 15 internal documents, okay.</p> <p>15 A. Yeah. Not many at all.</p> <p>16 Q. Just so the record -- you reviewed a total</p> <p>17 of 10 to 15 internal Ethicon documents, correct?</p> <p>18 A. See the reliance list. Yeah.</p> <p>19 Q. Fair to say that the bulk of the materials</p> <p>20 that you're relying on for your opinions in this case</p> <p>21 come from the medical literature and your clinical</p> <p>22 experience, correct?</p> <p>23 A. My knowledge, my training, my experience,</p> <p>24 the medical literature, my interaction with</p> <p>25 physicians, the totality of my career.</p>	<p>1 Q. Okay. Do you know what a DDSA is?</p> <p>2 A. No. I'm sorry. No.</p> <p>3 Q. I read in your report that you met</p> <p>4 Dr. Ulmsten; is that correct?</p> <p>5 A. I did.</p> <p>6 Q. Tell us a little bit about that.</p> <p>7 A. It was a weekend course. He was in at the</p> <p>8 course. I was fortunate enough, having trained with</p> <p>9 Dr. Klutke, to ride his coattails, so to speak, to</p> <p>10 get an opportunity to meet with Dr. Ulmsten. I can't</p> <p>11 remember if we went to dinner or not. But I got an</p> <p>12 opportunity to really spend some time with him and</p> <p>13 interact with him. I felt it was more than just</p> <p>14 meeting, hi, handshake with him. I interacted with</p> <p>15 him.</p> <p>16 Q. This is at -- when you were at Washington</p> <p>17 University at St. Louis or at --</p> <p>18 A. No, it was a weekend meeting. Yeah.</p> <p>19 Q. Okay. And do you recall where?</p> <p>20 A. Miami.</p> <p>21 Q. Miami?</p> <p>22 A. Okay.</p> <p>23 Q. So you got the opportunity to meet</p> <p>24 Dr. Ulmsten in Miami in what year?</p> <p>25 A. It was early on in my career. I can't</p>

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<p>1 remember specifically. It was -- it was maybe early 2 2000s. It was after my residency.</p> <p>3 Q. Okay. So sometime around early 2000, you 4 got the opportunity to meet the inventor of the TVT 5 Retropubic device, Dr. Ulmsten, in Miami, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And how long -- did you do a cadaver lab 8 course with him or did he teach you -- was it an 9 educational seminar or more of an opportunity to meet 10 the guy?</p> <p>11 A. Well, it was an educational meeting. But 12 in addition to learning from him in general, I got to 13 interact with him personally.</p> <p>14 Q. Okay. Sometime around early 2000 you met 15 Dr. Ulmsten and had the opportunity to get training 16 and educational insights from the inventor of the TVT 17 Retropubic, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And I take it then that you took that 20 training and educational insight that you got from 21 Dr. Ulmsten in 2000 and applied it in your practice 22 moving forward, correct?</p> <p>23 A. Yes.</p> <p>24 Q. Did you also get the chance to meet 25 Dr. de Leval?</p>	<p>1 A. The one that I remember is Bob Zipfel, 2 Robert Zipfel.</p> <p>3 Q. How long have you known Bob Zipfel?</p> <p>4 A. Oh, ten, twelve years.</p> <p>5 Q. How do you know Mr. Zipfel?</p> <p>6 A. Mr. Zipfel worked for Ethicon.</p> <p>7 Q. How did you meet?</p> <p>8 A. Probably one of the programs.</p> <p>9 Q. Okay. Do you consider him a friend?</p> <p>10 A. I consider him a friend.</p> <p>11 Q. Seems like you guys have a lot of 12 communications --</p> <p>13 A. Yes, I do.</p> <p>14 Q. -- back and forth?</p> <p>15 A. Yes, I do.</p> <p>16 Q. Okay. You still communicate to this day?</p> <p>17 A. Yes, we do.</p> <p>18 Q. Frequently?</p> <p>19 A. Define "frequently."</p> <p>20 Q. How often do you communicate with him?</p> <p>21 A. Not frequently.</p> <p>22 Q. It can get circular at times.</p> <p>23 A. I know it can.</p> <p>24 Q. It's the fun.</p> <p>25 A. Two or three times a year.</p>
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<p>1 A. No.</p> <p>2 Q. Did you ever travel to Liege, Belgium?</p> <p>3 A. No.</p> <p>4 Q. Did you -- were you ever invited to travel 5 to Liege, Belgium, to meet Dr. de Leval?</p> <p>6 A. No.</p> <p>7 Q. Did you ever travel to France for any 8 Ethicon-related activities?</p> <p>9 A. Yes.</p> <p>10 Q. Did Ethicon pay for you to travel to 11 France?</p> <p>12 A. I can't remember -- I know my travel was 13 covered, but I don't remember if I was paid.</p> <p>14 Q. Okay. When was that?</p> <p>15 A. 2006 or so. Early, late, mid-2006.</p> <p>16 Q. Okay. Sometime around 2006, Ethicon paid 17 for your travel to France, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And what did you do in France?</p> <p>20 A. I worked with Dr. Cosson.</p> <p>21 Q. When you went to France sometime in 2006, 22 did Ethicon employees also attend?</p> <p>23 A. Yes.</p> <p>24 Q. Do you recall which Ethicon employees 25 attended?</p>	<p>1 Q. How about this?</p> <p>2 A. Not frequently.</p> <p>3 Q. Okay. What does Bob Zipfel do at Ethicon?</p> <p>4 A. Now?</p> <p>5 Q. Sure.</p> <p>6 A. I don't believe he's employed at Ethicon 7 anymore.</p> <p>8 Q. When did he do?</p> <p>9 A. You know, all I can say is he wasn't a 10 representative, a field representative. I really 11 don't know what he did, but I know he wasn't a field 12 representative.</p> <p>13 Q. Okay. How do you know he wasn't a field 14 representative?</p> <p>15 A. I just know he didn't -- well, I didn't 16 think he was. I don't think he called on any 17 physicians. I'm sorry. I don't think he was a sales 18 representative. I misspoke.</p> <p>19 Q. Okay. Did any sales representatives also 20 attend this trip?</p> <p>21 A. Not that I recall.</p> <p>22 Q. Okay. Who is your current sales rep from 23 Ethicon?</p> <p>24 A. I don't know.</p> <p>25 Q. Do you have one?</p>

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<p>1 A. I don't know.</p> <p>2 Q. Okay. Do you recall any Ethicon sales</p> <p>3 representatives over the course of your career here</p> <p>4 in Danville?</p> <p>5 A. Yes.</p> <p>6 Q. Who?</p> <p>7 A. I believe my first was Lara Fawell. My</p> <p>8 second was Andrew Margolis. And then the -- kind of</p> <p>9 rolled over.</p> <p>10 Q. Turnover after --</p> <p>11 A. Turnover was pretty frequent. I know</p> <p>12 there was a guy, a couple of guys, and a girl -- I'm</p> <p>13 sorry. A woman.</p> <p>14 Apologize, Karen.</p> <p>15 Q. The first individual you listed, was that</p> <p>16 your first sales rep? What was her name again?</p> <p>17 Sorry.</p> <p>18 A. Lara Fawell.</p> <p>19 Q. Okay. Lara, was she your first sales rep</p> <p>20 from Ethicon?</p> <p>21 A. From Ethicon, yeah. From Ethicon, yes.</p> <p>22 Q. Okay. So sometime around 2000 when you</p> <p>23 came to Danville, she was your sales rep?</p> <p>24 A. 2000, 2001, she was, yes.</p> <p>25 Q. How long was she your sales rep for?</p>	<p>1 advice in the field of urology?</p> <p>2 A. Let's say I refer to them.</p> <p>3 Q. Okay. Are you also aware of journal</p> <p>4 articles that Dr. Raz has authored?</p> <p>5 A. Yes.</p> <p>6 Q. Have you actually -- has been on --</p> <p>7 coauthored an article together?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Maybe two?</p> <p>10 A. One or two.</p> <p>11 Q. Do you have any disagreements with Dr. Raz</p> <p>12 in the field of urology?</p> <p>13 MR. MORIARTY: Objection. Form.</p> <p>14 Go ahead and answer.</p> <p>15 THE WITNESS: Not knowing every opinion</p> <p>16 that Dr. Raz has, I can't tell you.</p> <p>17 BY MR. JONES:</p> <p>18 Q. On mesh, the use of mesh.</p> <p>19 A. Not knowing every opinion Dr. Raz has on</p> <p>20 the use of mesh, I can't tell you.</p> <p>21 Q. Okay. But it's fair to say you have a lot</p> <p>22 of respect for Dr. Raz in the field of urology?</p> <p>23 A. Yes.</p> <p>24 Q. He trained you?</p> <p>25 A. Yeah.</p>
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<p>1 A. You know, I can't remember. At some point</p> <p>2 she was reassigned, relocated.</p> <p>3 MR. JONES: Let's take a break,</p> <p>4 five-minute break. Fine with you guys?</p> <p>5 (A recess transpired from 6:18 p.m. until</p> <p>6 6:30 p.m.)</p> <p>7 MR. JONES: Let's get back on the record.</p> <p>8 BY MR. JONES:</p> <p>9 Q. Doctor, you had the opportunity to do a</p> <p>10 fellowship at UCLA under Dr. Shlomo Raz, correct?</p> <p>11 A. Yes.</p> <p>12 Q. That is a well-respected fellowship,</p> <p>13 correct?</p> <p>14 A. To some.</p> <p>15 Q. Do you have respect for Dr. Raz?</p> <p>16 A. I do.</p> <p>17 Q. Is Dr. Raz well respected in the field of</p> <p>18 urology?</p> <p>19 A. To some.</p> <p>20 Q. Are you familiar with any of the textbooks</p> <p>21 that Dr. Raz has authored in the field of urology?</p> <p>22 A. Yes.</p> <p>23 Q. Have -- do you own any of those textbooks?</p> <p>24 A. Yes.</p> <p>25 Q. Do you refer to them for expertise and</p>	<p>1 Q. Okay. Was Dr. -- do you know Eric</p> <p>2 Comiter?</p> <p>3 A. Yeah, I do.</p> <p>4 Q. Was he out there at the same time or</p> <p>5 different time?</p> <p>6 A. Different time.</p> <p>7 Q. Okay. After or before?</p> <p>8 A. I believe it was before.</p> <p>9 Q. Okay. Do you know where he practices</p> <p>10 currently?</p> <p>11 A. Currently, no.</p> <p>12 Q. You haven't talked to him in a while, it</p> <p>13 sounds like?</p> <p>14 A. No.</p> <p>15 Q. Okay. You did author -- you and</p> <p>16 Dr. Comiter coauthored a journal article together,</p> <p>17 though, correct?</p> <p>18 A. I don't remember.</p> <p>19 Q. Okay. We'll go over the CV later and go</p> <p>20 through them all.</p> <p>21 A. Okay.</p> <p>22 Q. Tell us how you got from UCLA to Danville.</p> <p>23 MR. MORIARTY: Well, there goes your two</p> <p>24 and a half hours.</p> <p>25 Go ahead.</p>

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<p>1 THE WITNESS: Could you be more specific?</p> <p>2 I mean -- you know, I can -- you know, I</p> <p>3 interviewed. I -- I interviewed a lot of</p> <p>4 positions. I looked at academic opportunities.</p> <p>5 I looked at private opportunities. I looked at</p> <p>6 large cities. I looked at medium-size cities.</p> <p>7 I looked at small cities. I really didn't</p> <p>8 restrict my search.</p> <p>9 I -- I came through Danville. Obviously</p> <p>10 was a community -- or it's -- I shouldn't say</p> <p>11 obviously. I mean, it was a community in need,</p> <p>12 it seemed to me, that it was a community in need</p> <p>13 of someone with my knowledge, training, and</p> <p>14 background and that I could provide a meaningful</p> <p>15 service to the community with my skills. And,</p> <p>16 you know, after really giving it very</p> <p>17 considerable thought with my wife, we decided to</p> <p>18 relocate here.</p> <p>19 BY MR. JONES:</p> <p>20 Q. Okay. Been here ever since, correct?</p> <p>21 A. Yes.</p> <p>22 Q. And at that point in time in 2000, did you</p> <p>23 start your own company in Danville?</p> <p>24 A. My own company.</p> <p>25 Q. Your own practice?</p>	<p>1 Q. Personally?</p> <p>2 A. Yes.</p> <p>3 Q. You haven't set up an LLC or a side</p> <p>4 company to accept payment, consultant payments?</p> <p>5 A. No.</p> <p>6 Q. Okay. What I want to do now -- should be</p> <p>7 fairly uncontroversial -- is I want to get the lay of</p> <p>8 the land for what mesh products you've used, when you</p> <p>9 used them, and how many times you used them.</p> <p>10 A. Okay.</p> <p>11 Q. And I think it might be easier to set out</p> <p>12 a little chart here. But let's start with Ethicon</p> <p>13 products. We'll start with the TVT line.</p> <p>14 How many times have you used TVT</p> <p>15 Retropubic?</p> <p>16 A. May I use a pen -- I'm just trying to,</p> <p>17 again, math.</p> <p>18 MR. ROSENBLATT: This isn't a written</p> <p>19 deposition.</p> <p>20 BY MR. JONES:</p> <p>21 Q. Sorry. He says you can't use a pen.</p> <p>22 A. Okay. That's fine.</p> <p>23 Q. I was trying to make it easier.</p> <p>24 A. Be patient with me as I do my math in my</p> <p>25 head.</p>
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<p>1 A. I joined a practice. I joined an existing</p> <p>2 practice.</p> <p>3 Q. Joined an existing practice?</p> <p>4 A. Yes.</p> <p>5 Q. And at the time, was that called the</p> <p>6 Danville Urologic Clinic, now operating as</p> <p>7 Southside -- or South -- what's the name of the</p> <p>8 clinic that you practice at right now?</p> <p>9 A. Southside Urology &amp; Nephrology.</p> <p>10 Q. Is that the same clinic you joined in</p> <p>11 2000 --</p> <p>12 A. Yes.</p> <p>13 Q. -- when you came to Danville? What is the</p> <p>14 Piedmont Institute for Incontinence?</p> <p>15 A. It's called the Piedmont Institute for</p> <p>16 Continence and Urinary Control.</p> <p>17 Q. Okay.</p> <p>18 A. It's the name I gave my specific aspect of</p> <p>19 the practice.</p> <p>20 Q. Is that a separate company that you've set</p> <p>21 up?</p> <p>22 A. No.</p> <p>23 Q. When Ethicon pays you as a consultant, do</p> <p>24 they pay you or the clinic?</p> <p>25 A. They pay me.</p>	<p>1 Q. He'll probably let you use a pen so long</p> <p>2 as I don't see it, though. Right?</p> <p>3 A. No, I don't need to go there. Which ones</p> <p>4 was it the one you were asking?</p> <p>5 Q. TVT Retropubic?</p> <p>6 A. Maybe 300.</p> <p>7 Q. 300. Okay.</p> <p>8 O. I'm going to go through them all.</p> <p>9 A. I know. I'm with you. I've got a number</p> <p>10 here, and I'm trying to figure out, based on the</p> <p>11 year, how many apparently I did. Let me give you</p> <p>12 that number. Hold on.</p> <p>13 MR. MORIARTY: Is there a question</p> <p>14 pending?</p> <p>15 BY MR. JONES:</p> <p>16 Q. There is.</p> <p>17 A. Change that to about 400.</p> <p>18 Q. TVT-R?</p> <p>19 A. Retropubic, yeah.</p> <p>20 Q. Okay.</p> <p>21 A. I don't know. 300 to 400.</p> <p>22 Q. 300 to 400?</p> <p>23 A. Yeah, that's fine.</p> <p>24 Q. And the question pending was TVT-O.</p> <p>25 A. 200 to 300.</p>

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<p>1 Q. Okay. TVT-Secur?</p> <p>2 A. 200.</p> <p>3 Q. TVT Abbrevos?</p> <p>4 A. What is my total right now? 400.</p> <p>5 Q. Okay. And Exact?</p> <p>6 A. Probably about 100.</p> <p>7 Q. Okay.</p> <p>8 A. Let me look at my numbers.</p> <p>9 Q. Yeah, sure.</p> <p>10 A. That's about right, give or take a couple</p> <p>11 hundred.</p> <p>12 Q. Give or take, rough estimates?</p> <p>13 A. Yeah.</p> <p>14 Q. Years.</p> <p>15 A. Okay.</p> <p>16 Q. Years and years. So let's start with TVT</p> <p>17 Retropubic, since that's the oldie but goodie.</p> <p>18 A. Started in -- hmm, 2004. Four years.</p> <p>19 Q. 2004 you started?</p> <p>20 A. No, no.</p> <p>21 Q. No.</p> <p>22 A. I started here in 2000. So about four</p> <p>23 years.</p> <p>24 Q. Okay. TVT-O next.</p> <p>25 A. Uh-huh. I did that probably until -- I</p>	<p>1 sling of choice is the TVT Abbrevo?</p> <p>2 A. Yes.</p> <p>3 Q. Do you still use the TVT Retropubic today?</p> <p>4 A. No.</p> <p>5 Q. Is it fair to say you stopped using the</p> <p>6 TVT Retropubic in 2004 but for limited use here and</p> <p>7 there after 2004?</p> <p>8 A. No. It's not fair to say. I -- I</p> <p>9 wouldn't want to say but for limited use. I would</p> <p>10 say -- my practice evolved. That's the best I can</p> <p>11 explain it to you.</p> <p>12 Q. How about this? Your sling of choice</p> <p>13 between 2000 and 2004 was the TVT Retropubic device,</p> <p>14 correct?</p> <p>15 A. Oh, absolutely.</p> <p>16 Q. Your sling of choice from 2004 to 2007 or</p> <p>17 2008 was the TVT Obturator, correct?</p> <p>18 A. Yes.</p> <p>19 Q. Your sling of choice from 2007 or 2008</p> <p>20 till 2010 was the TVT-Secur, correct?</p> <p>21 A. Yes.</p> <p>22 Q. Your sling of choice from 2010 till today</p> <p>23 is the TVT Abbrevo?</p> <p>24 A. Right.</p> <p>25 Q. Correct?</p>
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<p>1 did it a while. The Secur came out what -- in,</p> <p>2 trying to remember.</p> <p>3 Q. '6 or '7?</p> <p>4 A. '6 or '7. Maybe picked it up in '7.</p> <p>5 Probably did it until like 2007, 2008.</p> <p>6 Q. Okay. Then Secur, sometime 2007?</p> <p>7 A. 2008. And I did it until Abbrevo came</p> <p>8 out, which is like in 2010, I think. And I've done</p> <p>9 it pretty well since mostly. Majority of Abbrevos</p> <p>10 have been since 2010.</p> <p>11 Q. And Exact?</p> <p>12 A. I use, with the Abbrevo, since -- you</p> <p>13 know, throughout the course since the -- I did the</p> <p>14 Os, since it came out.</p> <p>15 Q. When did Exact come out?</p> <p>16 MR. ROSENBLATT: 2010.</p> <p>17 THE WITNESS: Yeah, that's what I thought.</p> <p>18 And I did -- I apologize. To clarify, I</p> <p>19 did some Os, Rs, S, you know.</p> <p>20 BY MR. JONES:</p> <p>21 Q. There's some overlap?</p> <p>22 A. There's overlap.</p> <p>23 Q. This is roughly speaking.</p> <p>24 A. Yeah.</p> <p>25 Q. All right. So sounds like today, your</p>	<p>1 A. Right.</p> <p>2 Q. You currently also use, in conjunction</p> <p>3 with the TVT Abbrevo, the TVT Exact device, correct?</p> <p>4 A. Yes.</p> <p>5 Q. Okay.</p> <p>6 A. And throughout the -- no, that's it.</p> <p>7 Fine, yes.</p> <p>8 Q. Okay. And I take it you also used other</p> <p>9 Ethicon products besides their transvaginal mesh</p> <p>10 products, correct?</p> <p>11 A. Yes.</p> <p>12 Q. What products would those include?</p> <p>13 A. For a brief period of time, I used the</p> <p>14 Monitor device. I used the Prolift device, and I use</p> <p>15 the Prosima. I never can pronounce that. Prosima.</p> <p>16 Q. I still haven't gotten it right.</p> <p>17 A. Prosima device, Prosima.</p> <p>18 Q. That's what I like to call it. Monitor,</p> <p>19 Prolift, Prosima. How did Morcellator?</p> <p>20 A. No.</p> <p>21 Q. Never used the Morcellator?</p> <p>22 A. I may have during my residency.</p> <p>23 Q. Okay. What about Prolift+M? Did you ever</p> <p>24 use that product?</p> <p>25 A. No.</p>

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<p>1 Q. Okay. Why not?</p> <p>2 A. My hospital didn't buy it.</p> <p>3 Q. Okay. Why not?</p> <p>4 A. You'd have to ask my hospital.</p> <p>5 Q. Did you ever try to persuade your hospital</p> <p>6 to buy that product?</p> <p>7 MR. MORIARTY: Objection. Go ahead.</p> <p>8 THE WITNESS: Persuade. What do you mean</p> <p>9 by "persuade"?</p> <p>10 BY MR. JONES:</p> <p>11 Q. Did you ever ask your hospital to purchase</p> <p>12 Prolift+M?</p> <p>13 A. Initially, yes. Yes, I did.</p> <p>14 Q. Okay. And they said no?</p> <p>15 A. They said no.</p> <p>16 Q. You don't know why they said no?</p> <p>17 A. I can't say with certainty why they said</p> <p>18 no.</p> <p>19 Q. Okay. What is it that you can't say with</p> <p>20 certainty that might be why they said no?</p> <p>21 MR. MORIARTY: Objection. Form.</p> <p>22 Otherwise, go ahead.</p> <p>23 THE WITNESS: Well, simply speculating, I</p> <p>24 think they were looking at dollars and cents.</p> <p>25 BY MR. JONES:</p>	<p>1 to your hospital purchasing board?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. What about Y-mesh, Ethicon Y-mesh,</p> <p>4 Artisyn Y-mesh? Did you ever use that one?</p> <p>5 A. I don't believe so.</p> <p>6 Q. Okay. What about, did you ever use</p> <p>7 Gynemesh PS flat mesh?</p> <p>8 A. Not in my own practice. I may have at</p> <p>9 UCLA. I don't know.</p> <p>10 Q. Okay. But not in your own practice?</p> <p>11 A. Not in my own practice.</p> <p>12 Q. Okay. How many Prolifts?</p> <p>13 A. Roughly 200.</p> <p>14 Q. How many Prosimas -- or Prosimas?</p> <p>15 A. 50, not that many.</p> <p>16 Q. Not that many. 50.</p> <p>17 When did you stop using Prolift?</p> <p>18 A. When it was no longer available.</p> <p>19 Q. When was that?</p> <p>20 A. When --</p> <p>21 Q. Let me stop you. Meaning when Ethicon</p> <p>22 stopped -- when Ethicon stopped selling Prolift is</p> <p>23 when you stopped using it?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. That would have been related to the</p>
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<p>1 Q. It was a business decision?</p> <p>2 A. Business decision.</p> <p>3 Q. Okay. That's a good point. Who makes the</p> <p>4 decision of what products are available at your</p> <p>5 hospitals?</p> <p>6 A. The surgeon and the materials manager.</p> <p>7 Q. You -- do you, as a surgeon, make the</p> <p>8 final decision of what products are available at the</p> <p>9 hospitals you operate at?</p> <p>10 A. What do you mean by "final"?</p> <p>11 Q. Well, we just went through, you asked the</p> <p>12 hospital to purchase Prolift+M. They said no.</p> <p>13 A. Okay.</p> <p>14 Q. To me, that indicates they're the ones</p> <p>15 making the final decision not you.</p> <p>16 A. No, that's not necessarily the case. I</p> <p>17 mean, I really didn't push that hard. I mean, one</p> <p>18 might argue that I didn't -- I didn't aggressively</p> <p>19 pursue it, so maybe I made the final decision.</p> <p>20 Q. Okay. So there's times when you ask your</p> <p>21 hospital to purchase a product that you push harder</p> <p>22 than other products, correct?</p> <p>23 A. Those were my words.</p> <p>24 Q. That's fair, right? There's some products</p> <p>25 you feel more strongly about than others when you go</p>	<p>1 FDA 522 orders issued on Ethicon, as far as you know?</p> <p>2 MR. MORIARTY: Objection. Go ahead.</p> <p>3 THE WITNESS: I don't know.</p> <p>4 BY MR. JONES:</p> <p>5 Q. You don't know one way or the other. Do</p> <p>6 you know what a 522 order is?</p> <p>7 A. I don't know specifically why they</p> <p>8 stopped --</p> <p>9 Q. Selling Prolift?</p> <p>10 A. -- selling it.</p> <p>11 Q. No one at Ethicon ever told you why they</p> <p>12 stopped selling Prolift?</p> <p>13 A. There was a lot of speculation, but I</p> <p>14 couldn't say with certainty why.</p> <p>15 Q. Did anybody ever tell you any reason --</p> <p>16 did any -- strike that.</p> <p>17 Did any Ethicon employee tell you a reason</p> <p>18 why Ethicon stopped selling Prolift?</p> <p>19 A. Repeat it again? I just want to make sure</p> <p>20 I understand your question.</p> <p>21 Q. Here's what I'm getting at.</p> <p>22 A. Yeah.</p> <p>23 Q. I just want to know, is there a single</p> <p>24 Ethicon employee --</p> <p>25 A. Any.</p>

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<p>1 Q. -- that said, "Hey, Dr. Carbone, here's</p> <p>2 why we're going to stop selling Ethicon -- or Ethicon</p> <p>3 Prolift mesh."</p> <p>4 A. No.</p> <p>5 Q. Okay. No Ethicon sales rep said,</p> <p>6 "Dr. Carbone, here's Ethicon's reason why we're not</p> <p>7 going to sell Ethicon Prolift mesh anymore?"</p> <p>8 A. Not without prefacing it with "I think."</p> <p>9 Q. Okay.</p> <p>10 A. Not with any definitive -- you had a</p> <p>11 declarative statement there. I never got a</p> <p>12 declarative statement from anybody.</p> <p>13 Q. What did they tell you they thought?</p> <p>14 MR. MORIARTY: Objection.</p> <p>15 Go ahead.</p> <p>16 THE WITNESS: They thought that -- how</p> <p>17 shall I put this? They thought that the company</p> <p>18 had done a tremendous number of FDA-approved</p> <p>19 randomized control trials and now they were</p> <p>20 being asked to repeat, at their expense, a</p> <p>21 litany of randomized control trials that were</p> <p>22 already FDA-approved in the first place, and it</p> <p>23 wasn't worth it.</p> <p>24 But again, one rep, said "I think."</p> <p>25 BY MR. JONES:</p>	<p>1 Q. Outside the business relationship.</p> <p>2 A. I would -- I would agree with that.</p> <p>3 Q. The information the sales -- Ethicon sales</p> <p>4 rep shared with you related to what they thought the</p> <p>5 reason --</p> <p>6 A. Hang on. You're going to have to slow</p> <p>7 down on me.</p> <p>8 Q. Sure. The information an Ethicon sales</p> <p>9 rep shared with you related to the reason this</p> <p>10 Ethicon sales rep believed Ethicon stopped selling</p> <p>11 Prolift was outside of your business relationship</p> <p>12 with this Ethicon sales rep?</p> <p>13 MR. MORIARTY: Objection. Form.</p> <p>14 THE WITNESS: Insofar as I followed you</p> <p>15 with that question, I would have to generally</p> <p>16 agree. But I can't because I really didn't</p> <p>17 follow it all that well.</p> <p>18 BY MR. JONES:</p> <p>19 Q. Okay. The information that Ethicon sales</p> <p>20 rep shared with you was outside of your business</p> <p>21 relationship with that sales rep.</p> <p>22 A. Yes.</p> <p>23 Q. Okay. When did you start using Prolift?</p> <p>24 A. Around 2006.</p> <p>25 Q. When did you start using Prosima?</p>
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<p>1 Q. One Ethicon sales rep in their role as a</p> <p>2 sales representative for Ethicon told you they</p> <p>3 thought Prolift mesh was not going to be sold by</p> <p>4 Ethicon for the reasons you just stated, correct?</p> <p>5 A. Let me -- let me ask you. What did you</p> <p>6 mean by "in their role as a" --</p> <p>7 Q. Meaning this was -- they weren't saying,</p> <p>8 "Hey, I'm an Ethicon sales rep, but tonight we're</p> <p>9 going to go bowling and hang out and have a few beers</p> <p>10 and I'm going to tell you personally why I think it</p> <p>11 is."</p> <p>12 MR. MORIARTY: Objection. Because I have</p> <p>13 no idea if there's even a question there.</p> <p>14 Go ahead and answer if you understand.</p> <p>15 BY MR. JONES:</p> <p>16 Q. Yeah, we're just trying -- you get what I</p> <p>17 mean, right?</p> <p>18 A. Right. I don't think they were telling me</p> <p>19 that as an official -- in their role as an official</p> <p>20 Ethicon representative.</p> <p>21 Q. Okay. Kind of maybe information they were</p> <p>22 telling you in the context of a personal relationship</p> <p>23 between you and the sales rep?</p> <p>24 A. Again, what are you saying "personal"? I</p> <p>25 mean --</p>	<p>1 A. Again, I can't remember specifically. I</p> <p>2 didn't do that many. When did it come out?</p> <p>3 Q. Say 2008.</p> <p>4 A. 2009.</p> <p>5 Q. Okay. 2008-2009?</p> <p>6 A. 2008-2009.</p> <p>7 Q. How come you didn't do very many?</p> <p>8 A. I -- I like the product. I felt the --</p> <p>9 there were advantages, disadvantages. I felt one of</p> <p>10 the advantages was the trocharless insertion; one of</p> <p>11 the disadvantages was the trocharless insertion. And</p> <p>12 so I tried it.</p> <p>13 Q. Sounds like Prosima in theory was a good</p> <p>14 idea; in practice, maybe not so much?</p> <p>15 MR. MORIARTY: Objection.</p> <p>16 Go ahead.</p> <p>17 THE WITNESS: I can't say I didn't do it</p> <p>18 because it wasn't a good idea. I just didn't do</p> <p>19 all that many.</p> <p>20 BY MR. JONES:</p> <p>21 Q. Okay. Did you have any failures with</p> <p>22 Prosima?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. How many?</p> <p>25 A. I can't remember specifically to the</p>

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<p>1 Prosima device. I kind of lumped all -- I can't</p> <p>2 remember specifically to the Prosima device.</p> <p>3 Q. What other device?</p> <p>4 A. What do you mean by that?</p> <p>5 Q. You're saying -- did you have failures</p> <p>6 with Prolift as well?</p> <p>7 A. I did.</p> <p>8 Q. How many?</p> <p>9 A. Let's say between Prosima and Prolift, 20,</p> <p>10 25.</p> <p>11 Q. Okay. Do you have an exact number?</p> <p>12 A. No.</p> <p>13 Q. Have you ever endeavored to do a survey or</p> <p>14 study of your exact complication rate?</p> <p>15 MR. MORIARTY: Objection. Go ahead.</p> <p>16 THE WITNESS: Not my exact complication</p> <p>17 rate.</p> <p>18 BY MR. JONES:</p> <p>19 Q. Okay. How about have you ever done a</p> <p>20 survey or study to discover your exact failure rate?</p> <p>21 MR. MORIARTY: Objection. Form.</p> <p>22 THE WITNESS: Not my exact failure rate.</p> <p>23</p> <p>24 BY MR. JONES:</p> <p>25 Q. So you can't tell us one way or the other</p>	<p>1 Q. Why don't you currently use the TVT</p> <p>2 Retropubic device?</p> <p>3 A. The retropubic device that I use is the</p> <p>4 Exact.</p> <p>5 Q. Why don't you use the TVT Retropubic</p> <p>6 device?</p> <p>7 MR. MORIARTY: Objection.</p> <p>8 Go ahead.</p> <p>9 THE WITNESS: Because the TVT Exact is</p> <p>10 available.</p> <p>11 BY MR. JONES:</p> <p>12 Q. Do you prefer the TVT Exact device over</p> <p>13 the TVT Retropubic device?</p> <p>14 A. Yes.</p> <p>15 Q. Why?</p> <p>16 A. Just is more comfortable in my hands.</p> <p>17 Q. Are there any differences between the mesh</p> <p>18 used in the TVT Exact device and the mesh used in the</p> <p>19 TVT Retropubic device?</p> <p>20 A. I don't recall if the TVT Retropubic</p> <p>21 device had the blue mesh.</p> <p>22 Q. Other than the color -- the dye, the blue</p> <p>23 color dye in the mesh -- are there any other</p> <p>24 differences between the TVT Retropubic device and the</p> <p>25 TVT Exact device?</p>
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<p>1 your precise success rate with the use of mesh,</p> <p>2 correct?</p> <p>3 A. Not --</p> <p>4 MR. MORIARTY: Objection.</p> <p>5 THE WITNESS: -- my precise.</p> <p>6 BY MR. JONES:</p> <p>7 Q. Have you ever attempted to create a</p> <p>8 registry with your mesh patients? A registry that</p> <p>9 tracks your patients, say, five years down the road?</p> <p>10 A. No.</p> <p>11 Q. If the TVT-Secur device was still sold by</p> <p>12 Ethicon today, would you use it?</p> <p>13 MR. MORIARTY: I'm sorry. Could you just</p> <p>14 read that back?</p> <p>15 (Whereupon the Court Reporter read the</p> <p>16 previous question.)</p> <p>17 MR. MORIARTY: Thank you.</p> <p>18 THE WITNESS: Not likely.</p> <p>19 BY MR. JONES:</p> <p>20 Q. Why not?</p> <p>21 A. I like the device fair enough. I think it</p> <p>22 had a good success and safety profile in my hands. I</p> <p>23 feel more confident with the Abbrevio that I get the</p> <p>24 ends of the mesh into the exact position that I want</p> <p>25 them in in the obturator fascia.</p>	<p>1 A. I believe that the Exact device has a</p> <p>2 laser cut, and I don't think the previous TVT device</p> <p>3 was laser-cut. I think it was mechanically cut</p> <p>4 still.</p> <p>5 Q. Okay. Is there a difference between TVT</p> <p>6 laser-cut mesh and TVT mechanical-cut mesh?</p> <p>7 MR. MORIARTY: Objection. Go ahead.</p> <p>8 THE WITNESS: Well, in the way it's cut.</p> <p>9 BY MR. JONES:</p> <p>10 Q. Is there a clinical difference between the</p> <p>11 two?</p> <p>12 A. Is there a -- no.</p> <p>13 Q. Okay. When you -- is there a difference</p> <p>14 in your hands between the TVT laser cut mesh and TVT</p> <p>15 mechanical cut mesh?</p> <p>16 A. No.</p> <p>17 Q. Can -- if you picked them both up, could</p> <p>18 you tell a difference between the two?</p> <p>19 MR. MORIARTY: Objection. I assume you</p> <p>20 mean without reading on the package which it</p> <p>21 might be? With that assumption --</p> <p>22 BY MR. JONES:</p> <p>23 Q. If you picked them up?</p> <p>24 MR. MORIARTY: They might be in a package.</p> <p>25 MR. JONES: Oh, okay. Thanks.</p>

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<p>1 MR. MORIARTY: Sure. No problem. Thanks.</p> <p>2 Go ahead.</p> <p>3 BY MR. JONES:</p> <p>4 Q. Yeah, just answer it.</p> <p>5 A. Yeah. I could feel the difference.</p> <p>6 Q. You can feel the difference between the</p> <p>7 two?</p> <p>8 A. Yes.</p> <p>9 Q. What's the difference?</p> <p>10 A. One has a little -- the edges feel</p> <p>11 different.</p> <p>12 Q. What's the difference in the edges between</p> <p>13 the TVT mechanical-cut mesh and the TVT laser-cut</p> <p>14 mesh?</p> <p>15 A. It's hard to describe because they're not</p> <p>16 that much different. I guess the laser-cut has more</p> <p>17 of a -- a beaded feel, whereas the other one doesn't</p> <p>18 have that beaded feel.</p> <p>19 Q. Define "beaded feel."</p> <p>20 A. Yeah.</p> <p>21 Q. Here's the deal, Dr. Carbone. At some</p> <p>22 point, a juror may listen to this testimony.</p> <p>23 A. Yeah, I understand.</p> <p>24 Q. Explain to the juror what you mean by the</p> <p>25 laser-cut mesh used in TVT has a beaded feel compared</p>	<p>1 Q. Do you know the pore size Exact</p> <p>2 measurement? What's the -- how about this? That was</p> <p>3 one of my horrible questions.</p> <p>4 A. I didn't -- you're using that word</p> <p>5 "exact." Is that "Exact" with a capital E or "exact"</p> <p>6 with a lowercase?</p> <p>7 Q. Thanks, thanks. That's another one of my</p> <p>8 horrible questions.</p> <p>9 MR. ROSENBLATT: I'm keeping a list.</p> <p>10 MR. JONES: It's going to be a long list,</p> <p>11 Paul.</p> <p>12 BY MR. JONES:</p> <p>13 Q. What is the pore size of the TVT laser-cut</p> <p>14 mesh?</p> <p>15 A. Greater than 75 microns.</p> <p>16 Q. Is the TVT -- is the pore size of the TVT</p> <p>17 laser-cut mesh greater than a thousand microns?</p> <p>18 MR. MORIARTY: Greater than a thousand</p> <p>19 microns? Objection.</p> <p>20 Go ahead.</p> <p>21 THE WITNESS: I don't believe so.</p> <p>22 BY MR. JONES:</p> <p>23 Q. You don't believe so? Okay.</p> <p>24 A. Huh-uh.</p> <p>25 Q. Do you know the effective porosity of the</p>
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<p>1 to the mechanical-cut mesh using TVT.</p> <p>2 A. It feels smoother.</p> <p>3 Q. Is there a difference in stiffness between</p> <p>4 the TVT laser-cut mesh and TVT mechanical-cut mesh?</p> <p>5 A. Not that I can feel.</p> <p>6 Q. So when you pick up TVT mechanical mesh</p> <p>7 and compare it to TVT laser-cut mesh, you can't</p> <p>8 ascertain any difference in stiffness?</p> <p>9 A. No.</p> <p>10 Q. Okay. The only difference when you hold</p> <p>11 the TVT mechanical-cut mesh in your hand and compare</p> <p>12 to the TVT laser-cut mesh is the edge of the mesh,</p> <p>13 correct?</p> <p>14 A. Pretty much, yes.</p> <p>15 Q. And the way you've described it is the TVT</p> <p>16 laser-cut mesh as compared to the TVT mechanical-cut</p> <p>17 mesh has a beaded feel or smoother feel to the edge</p> <p>18 in the mesh, correct?</p> <p>19 A. Correct.</p> <p>20 Q. Currently you use TVT Exact, which uses</p> <p>21 laser-cut mesh, correct?</p> <p>22 A. Yes.</p> <p>23 Q. Do you know the pore size of the laser-cut</p> <p>24 mesh used in TVT Exact?</p> <p>25 A. Greater than 75 microns.</p>	<p>1 TVT laser-cut mesh?</p> <p>2 A. Greater than 75 microns.</p> <p>3 Q. Are you familiar with the term "effective</p> <p>4 porosity"?</p> <p>5 A. No.</p> <p>6 Q. Do you know the pore size of the TVT mesh</p> <p>7 after tension is placed on the mesh?</p> <p>8 MR. MORIARTY: Objection.</p> <p>9 Go ahead.</p> <p>10 THE WITNESS: Hmm. No.</p> <p>11 BY MR. JONES:</p> <p>12 Q. Is the pore size of the TVT mesh greater</p> <p>13 than 500 microns?</p> <p>14 A. No.</p> <p>15 Q. Is the pore size of the TVT mesh greater</p> <p>16 than 250 microns?</p> <p>17 A. No.</p> <p>18 Q. Is the pore size of the TVT mesh greater</p> <p>19 than 125 microns?</p> <p>20 MR. MORIARTY: Objection.</p> <p>21 Go ahead.</p> <p>22 THE WITNESS: Not that I believe.</p> <p>23</p> <p>24 BY MR. MORIARTY:</p> <p>25 Q. Do you know the density of the TVT mesh?</p>

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<p>1 A. No.</p> <p>2 Q. Do you know the stiffness of the TVT mesh?</p> <p>3 A. No.</p> <p>4 Q. Do you know the antioxidants that Ethicon</p> <p>5 uses in the TVT mesh?</p> <p>6 A. The antioxidants?</p> <p>7 Q. Sure. Do you know whether or not Ethicon</p> <p>8 adds antioxidants to the TVT mesh or not?</p> <p>9 A. Aren't antioxidants used in all Prolene?</p> <p>10 I believe antioxidants are used in all Prolene, and I</p> <p>11 don't know what antioxidants are used.</p> <p>12 Q. There you go. That's my question. You</p> <p>13 don't know what antioxidants are used in TVT mesh,</p> <p>14 correct?</p> <p>15 A. Correct.</p> <p>16 Q. Okay. Do you know the name of the resin,</p> <p>17 polypropylene resin, used in TVT mesh?</p> <p>18 A. The resin?</p> <p>19 Q. (Nodding head up and down.)</p> <p>20 A. No.</p> <p>21 Q. Do you consider yourself a materials</p> <p>22 expert?</p> <p>23 A. Well, what do you mean by "materials</p> <p>24 expert"?</p> <p>25 Q. Do you -- will you be -- do you consider</p>	<p>1 Q. Okay. That's not -- I didn't ask about</p> <p>2 Level 1. I'm just asking about any medical</p> <p>3 literature.</p> <p>4 MR. MORIARTY: Objection.</p> <p>5 Go ahead.</p> <p>6 THE WITNESS: Geez. I guess I'm sure, as</p> <p>7 I've gone around -- I mean, I've done a lot of</p> <p>8 review. I'm sure there is very low-evidence</p> <p>9 material out there that would suggest that.</p> <p>10 BY MR. JONES:</p> <p>11 Q. Okay. So it's fair to say that in your</p> <p>12 review, you've come across medical literature that</p> <p>13 concludes mesh degrades inside the patient, correct?</p> <p>14 A. When you say "inside the patient," are you</p> <p>15 talking about explanted materials or are you talking</p> <p>16 about materials that are still inside the patient?</p> <p>17 Q. Either. We'll go with explant. How about</p> <p>18 that?</p> <p>19 A. Well, there's literature -- not good</p> <p>20 literature -- there's literature that suggests that</p> <p>21 TVT or -- yeah, polypropylene TVT mesh might degrade.</p> <p>22 Yeah.</p> <p>23 Q. Is there -- do you recall what literature</p> <p>24 is that? Do you recall any authors, titles?</p> <p>25 A. No.</p>
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<p>1 yourself an expert in the properties of the TVT mesh?</p> <p>2 A. I believe that I am an expert in the</p> <p>3 clinical properties of the TVT mesh. If you ask me</p> <p>4 do I have a Ph.D. in material science? No, I don't.</p> <p>5 Have I spoken with material scientists? Yes. Have</p> <p>6 I, you know, interacted with them? Have I talked to</p> <p>7 them about the Amid classification? Have I taught on</p> <p>8 the mesh itself? Have I used -- most importantly,</p> <p>9 have I used the mesh -- my experience with the mesh</p> <p>10 clinically and how it works in vivo?</p> <p>11 I would say that I have an expert -- I</p> <p>12 have a -- a knowledge and a -- I have knowledge and</p> <p>13 training and experience that would allow me to</p> <p>14 provide expert opinion in that context.</p> <p>15 Q. Does the TVT mesh degrade inside a woman?</p> <p>16 A. I don't believe so.</p> <p>17 Q. Have you reviewed any test by Ethicon of</p> <p>18 the mesh used in TVT that concludes the mesh does</p> <p>19 degrade?</p> <p>20 A. Say it again?</p> <p>21 Q. Sure. Have you reviewed any medical</p> <p>22 literature that disagrees with you that mesh does not</p> <p>23 degrade inside a patient?</p> <p>24 A. I have not reviewed any Level 1 material</p> <p>25 randomized controlled trials to that effect.</p>	<p>1 Q. Can you name one as you sit here today?</p> <p>2 A. As I sit here today, I cannot recall</p> <p>3 specifically.</p> <p>4 Q. Clavé. Does that ring a bell for you?</p> <p>5 A. Clavé. Name sounds familiar, yeah. I</p> <p>6 think, yeah.</p> <p>7 Q. You think that's one of them?</p> <p>8 A. Yeah.</p> <p>9 Q. Probably?</p> <p>10 A. Probably.</p> <p>11 Q. Okay. Have you reviewed any testing done</p> <p>12 by Ethicon on the mesh which discusses degradation of</p> <p>13 mesh?</p> <p>14 MR. MORIARTY: Objection.</p> <p>15 Go ahead.</p> <p>16 THE WITNESS: Now I guess I'm going to go</p> <p>17 back to your question, and I clarified it</p> <p>18 before. In vivo?</p> <p>19 BY MR. JONES:</p> <p>20 Q. In vivo.</p> <p>21 A. Ethicon -- repeat your question.</p> <p>22 Q. Have you reviewed any Ethicon testing of</p> <p>23 mesh in vivo that suggests the mesh degrades?</p> <p>24 A. I don't recall.</p> <p>25 Q. Okay. How about not in vivo?</p>

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<p>1 MR. MORIARTY: Objection to form.</p> <p>2 THE WITNESS: I don't recall if it was --</p> <p>3 I mean, again, your whole question was</p> <p>4 Ethicon -- not medical literature now. You're</p> <p>5 talking about Ethicon-related documents?</p> <p>6 BY MR. JONES:</p> <p>7 Q. Correct.</p> <p>8 A. Ex vivo degradation. Not that I recall.</p> <p>9 Q. Okay. Is degradation of the mesh inside a</p> <p>10 patient a potential risk?</p> <p>11 MR. MORIARTY: Objection. Form.</p> <p>12 Go ahead.</p> <p>13 THE WITNESS: What do you mean by</p> <p>14 "potential"?</p> <p>15 BY MR. JONES:</p> <p>16 Q. Could it happen?</p> <p>17 A. I mean, I can't -- let me put it this way.</p> <p>18 I can't say as an expert that it can happen. I can</p> <p>19 speculate it could happen. But I can't say that I</p> <p>20 have any evidence, as a materials expert in the</p> <p>21 context that I talked to you about, that it degrades</p> <p>22 in the body.</p> <p>23 Q. Okay. Would it be speculation for you as</p> <p>24 an expert to say it absolutely does not degrade</p> <p>25 inside the body?</p>	<p>1 A. Yeah, I've looked at them.</p> <p>2 Q. Never seen any signs of degradation on any</p> <p>3 mesh explants you've looked at from patients?</p> <p>4 A. What do you mean by "signs"?</p> <p>5 Q. Has the material broken down whatsoever?</p> <p>6 A. I haven't seen any signs.</p> <p>7 Q. Okay. Is the TVT mesh inside the patient</p> <p>8 inert?</p> <p>9 MR. MORIARTY: Objection. Form.</p> <p>10 THE WITNESS: Again, what do you mean by</p> <p>11 "inert"? I mean -- let me just ask, what do you</p> <p>12 mean by "inert"? What time frame are you</p> <p>13 talking about as being inert?</p> <p>14 BY MR. JONES:</p> <p>15 Q. The time frame that the mesh is inside the</p> <p>16 patient, which --</p> <p>17 A. Okay. Let me answer it to you this way.</p> <p>18 Initially, there is an inflammatory reaction. The</p> <p>19 body responds by having neutrophils and macrophages</p> <p>20 and fibroblasts to lay down collagen covering and</p> <p>21 incorporating into the mesh. And once that has been</p> <p>22 incorporated, I believe it's inert.</p> <p>23 Q. Okay. For -- and it's inert for as long</p> <p>24 as the mesh is inside the patient, correct?</p> <p>25 A. In my -- yes, yes, yeah.</p>
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<p>1 MR. MORIARTY: Objection.</p> <p>2 THE WITNESS: You got a lot of negatives</p> <p>3 there.</p> <p>4 MR. MORIARTY: Objection to form.</p> <p>5 THE WITNESS: Yeah. Could you restate the</p> <p>6 question?</p> <p>7 BY MR. JONES:</p> <p>8 Q. Sure. You get what I'm getting at. You</p> <p>9 said, it's speculation for me as an expert to say</p> <p>10 it's a potential risk that the mesh degrades.</p> <p>11 A. Okay.</p> <p>12 Q. My question is, is it speculation for you</p> <p>13 as an expert to say the mesh absolutely does not</p> <p>14 degrade in vivo?</p> <p>15 MR. MORIARTY: Objection. Form.</p> <p>16 THE WITNESS: In the context of my</p> <p>17 expertise on mesh and its use in the patient, I</p> <p>18 believe -- I will render the opinion to a</p> <p>19 reasonable degree of medical certainty that it</p> <p>20 does not degrade.</p> <p>21 BY MR. JONES:</p> <p>22 Q. Okay. Have you ever reviewed explanted</p> <p>23 mesh samples from patients?</p> <p>24 A. What do you mean by "reviewed"?</p> <p>25 Q. Looked at them.</p>	<p>1 Q. Is there a difference in the inflammatory</p> <p>2 response between TVT mesh and Prolift mesh?</p> <p>3 A. Is there a difference in the inflammatory</p> <p>4 response? No.</p> <p>5 Q. Does pore size affect the inflammatory</p> <p>6 response?</p> <p>7 A. Many things affect it. Pore size is one</p> <p>8 of them.</p> <p>9 Q. Does the density of the mesh affect the</p> <p>10 level of the inflammatory response?</p> <p>11 A. I don't believe Amid's classification</p> <p>12 included density.</p> <p>13 Q. Does the amount of mesh affect the</p> <p>14 inflammatory response?</p> <p>15 A. Say it again.</p> <p>16 Q. Does the amount of mesh affect the</p> <p>17 inflammatory response inside the patient?</p> <p>18 A. The -- no, not the inflammatory response.</p> <p>19 Q. Okay. Is less mesh a benefit to the</p> <p>20 patient?</p> <p>21 MR. MORIARTY: Objection. Form.</p> <p>22 THE WITNESS: I guess I got to ask you</p> <p>23 what you mean by "benefit."</p> <p>24 BY MR. JONES:</p> <p>25 Q. Is a smaller piece of mesh implanted in a</p>

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<p>1 woman's vagina safer for the woman?</p> <p>2 A. Again, you know, there's --</p> <p>3 Q. Less complications?</p> <p>4 A. Fewer complications. Well, the -- the</p> <p>5 reason I can't give you -- and I'm not trying to be</p> <p>6 difficult. But the reason why I can't give you a</p> <p>7 straight answer to that question is most of the -- or</p> <p>8 the -- the Level 1 clinical data has to do not only</p> <p>9 with just the mesh, but the procedures that are --</p> <p>10 that utilize the mesh.</p> <p>11 So when you say complications, you see,</p> <p>12 you can't separate the two. So I can't give you, you</p> <p>13 know, is less mesh -- the technique is important too.</p> <p>14 Q. Okay. If the technique is the same, is</p> <p>15 less mesh implanted in a woman's vagina safer for</p> <p>16 that woman in that she will have likelihood of less</p> <p>17 complications?</p> <p>18 MR. MORIARTY: Objection. Go ahead.</p> <p>19 THE WITNESS: In general, I would agree</p> <p>20 with that statement.</p> <p>21 MR. JONES: Okay. You guys want to take a</p> <p>22 break and eat?</p> <p>23 (A recess transpired from 7:21 p.m. until</p> <p>24 7:49 p.m.)</p> <p>25 BY MR. JONES:</p>	<p>1 current litigation that we're discussing here today,</p> <p>2 have you ever acted as an expert in litigation?</p> <p>3 A. Expert in -- no.</p> <p>4 Q. No. So besides the transvaginal mesh</p> <p>5 litigation that we're discussing here today and</p> <p>6 Farmer versus Willard, you've never acted as an</p> <p>7 expert witness in any litigation, correct?</p> <p>8 A. I have reviewed cases -- if I recall</p> <p>9 correctly, this was asking for what depositions I</p> <p>10 have provided. That's not the question that you</p> <p>11 asked I understand now?</p> <p>12 Q. Correct.</p> <p>13 A. So the question you're asking is what?</p> <p>14 Q. Cases you've acted as an expert.</p> <p>15 A. Acted. I have acted in many more.</p> <p>16 Q. Okay. Many more. How many?</p> <p>17 A. Probably about 15 to 20.</p> <p>18 Q. How many?</p> <p>19 A. 15 to 20.</p> <p>20 Q. Okay. 15 to 20 cases you've acted as an</p> <p>21 expert in. Have you issued reports in those cases?</p> <p>22 A. No.</p> <p>23 Q. Okay. Did those cases involve</p> <p>24 transvaginal mesh?</p> <p>25 A. No.</p>
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<p>1 Q. Back on the record. Doctor, ready to</p> <p>2 proceed?</p> <p>3 A. Yes, sir.</p> <p>4 Q. Great. Thanks.</p> <p>5 We noticed in your prior testimony, you</p> <p>6 had listed Farmer versus Willard, September 2014, a</p> <p>7 video deposition, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. What is Farmer versus Willard</p> <p>10 about?</p> <p>11 A. It was a medical malpractice case -- which</p> <p>12 one was the v and which one was the -- so Willard was</p> <p>13 the physician, Farmer was the patient. He had</p> <p>14 epididymo-orchitis. He didn't -- Willard treated him</p> <p>15 but didn't have him scheduled for follow-up.</p> <p>16 Patient presented a long time later on</p> <p>17 with a scrotum -- an acute scrotum, needed an</p> <p>18 orchiectomy. And they felt that Willard should have</p> <p>19 had him follow up earlier. And I agreed.</p> <p>20 Q. You acted as an expert in the matter of</p> <p>21 Farmer versus Willard, correct?</p> <p>22 A. Yes, a plaintiff's expert.</p> <p>23 Q. You were expert for the plaintiff?</p> <p>24 A. Yes.</p> <p>25 Q. Other than Farmer versus Willard and the</p>	<p>1 Q. Is today the first time you have ever</p> <p>2 given expert testimony as an expert in a transvaginal</p> <p>3 mesh case?</p> <p>4 A. To the best of my recollection, yeah.</p> <p>5 Q. Is this case the first time you've ever</p> <p>6 acted as an expert in litigation in a case involving</p> <p>7 transvaginal mesh?</p> <p>8 A. Again, acted as an expert in transvaginal</p> <p>9 litigation mesh -- or transvaginal mesh litigation?</p> <p>10 Q. (Nodding head up and down.)</p> <p>11 A. And that means both the TVT polypropylene</p> <p>12 Prolene mesh and the -- okay -- and the Prolift</p> <p>13 polypropylene mesh.</p> <p>14 Q. Any mesh in transvaginal --</p> <p>15 A. To the best of my recollection, none of</p> <p>16 the med mal -- and they were all med mal -- cases</p> <p>17 that I reviewed were -- involved TVT polypropylene or</p> <p>18 Prolift polypropylene mesh.</p> <p>19 Q. Okay. Great. Perfect. Is this case the</p> <p>20 first time you've acted as an expert in the design</p> <p>21 and safety of a device?</p> <p>22 A. Expert in the design and safety. I mean,</p> <p>23 the -- what do you mean by "expert"? I think we've</p> <p>24 had this discussion before with respect to the expert</p> <p>25 in the materials. But now you're talking about</p>

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<p>1 design and safety; is that correct? Different?</p> <p>2 Q. (Nodding head up and down.)</p> <p>3 A. So I ask again the same question. What do</p> <p>4 you mean by "expert in design and safety"?</p> <p>5 Q. You don't have -- you don't understand my</p> <p>6 question of whether -- are you an expert in this case</p> <p>7 on the design of the TVT device?</p> <p>8 MR. MORIARTY: Objection.</p> <p>9 Go ahead.</p> <p>10 THE WITNESS: Inasmuch as -- I'm not an</p> <p>11 engineer. Okay? But inasmuch as I'm familiar</p> <p>12 with the design, I've used the design, I've been</p> <p>13 trained, I have experience with the design, I've</p> <p>14 read the literature regarding the design, I've</p> <p>15 used it clinically, I feel like I am an expert.</p> <p>16 But -- in that context, I believe I'm an expert.</p> <p>17 I'm not -- I'm saying that I'm not an engineer.</p> <p>18 I can't speak with any --</p> <p>19 BY MR. JONES:</p> <p>20 Q. Okay. Here's my question.</p> <p>21 A. Go ahead.</p> <p>22 Q. Have you ever been asked by a medical</p> <p>23 device company prior to Ethicon in this case to be an</p> <p>24 expert in litigation?</p> <p>25 A. Repeat it. Seriously. Just want to make</p>	<p>1 Do you have any reason to disagree with</p> <p>2 that?</p> <p>3 A. I have no reason to disagree with that.</p> <p>4 Q. Okay. And am I correct in saying, between</p> <p>5 the years 2003 to 2012, Ethicon paid you, according</p> <p>6 to Exhibit 5, \$452,398?</p> <p>7 MR. MORIARTY: Objection.</p> <p>8 Go ahead.</p> <p>9 THE WITNESS: As a consultant, yes.</p> <p>10 BY MR. JONES:</p> <p>11 Q. Did they pay you any other money outside</p> <p>12 of your role as consultant?</p> <p>13 A. No.</p> <p>14 Q. So between the years 2003 to 2012, Ethicon</p> <p>15 paid you 452,398, correct?</p> <p>16 A. Correct.</p> <p>17 Q. Okay. When did Ethicon first contact you</p> <p>18 to be an expert in this case?</p> <p>19 A. You know, I don't remember. Obviously</p> <p>20 sometime before 2003.</p> <p>21 Q. When did -- I probably did a bad job</p> <p>22 asking that question.</p> <p>23 A. I apologize.</p> <p>24 Q. That's on me. Ethicon -- I assume Ethicon</p> <p>25 contacted you and said, "Hey, we've got this</p>
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<p>1 sure I get it right.</p> <p>2 Q. Have you ever been asked by a medical</p> <p>3 device company other than Ethicon to be an expert in</p> <p>4 litigation?</p> <p>5 A. To the best of my recollection, I don't</p> <p>6 believe any of the medical malpractice cases involved</p> <p>7 medical devices.</p> <p>8 Q. Now I've got to ask you again. Yes or no.</p> <p>9 To the best of your recollection, has a medical</p> <p>10 device company other than Ethicon ever asked you to</p> <p>11 act as an expert in litigation?</p> <p>12 A. Is it the same question?</p> <p>13 Q. Yes or no?</p> <p>14 A. Was my answer inadequate?</p> <p>15 Q. Yes or no?</p> <p>16 A. Not that I recall.</p> <p>17 Q. Okay. Perfect.</p> <p>18 A. Okay.</p> <p>19 Q. We went back and we did tally up the</p> <p>20 payments from Exhibit 5.</p> <p>21 A. Okay.</p> <p>22 Q. So you have Exhibit 5 in front of you, and</p> <p>23 we added up those payments from Ethicon to you</p> <p>24 between the years 2003 to 2012. And the total I'll</p> <p>25 represent to you is \$452,398.</p>	<p>1 litigation going on. We want you to be an expert."</p> <p>2 A. Oh, I apologize.</p> <p>3 Q. Let me reask the question so the record's</p> <p>4 clear.</p> <p>5 A. Go ahead.</p> <p>6 Q. When did Ethicon first contact you to be</p> <p>7 a -- to ask you to be an expert in this litigation?</p> <p>8 A. May of last year. Sometime in the spring,</p> <p>9 I believe.</p> <p>10 Q. When did you first start working on the</p> <p>11 case?</p> <p>12 A. Sometime after May of last year some --</p> <p>13 you know, in the spring of last year, summer of last</p> <p>14 year.</p> <p>15 Q. Okay. When did you draft your TVT report?</p> <p>16 A. Earlier this year, probably maybe January,</p> <p>17 February.</p> <p>18 Q. Are all the opinions you intend to offer</p> <p>19 in this case contained within your report?</p> <p>20 MR. MORIARTY: Objection.</p> <p>21 Go ahead.</p> <p>22 THE WITNESS: Well, I -- I suppose it's</p> <p>23 what you ask me. Okay.</p> <p>24 BY MR. JONES:</p> <p>25 Q. What opinions do you intend to offer in</p>

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<p>1 this case? Perfect opportunity.</p> <p>2 MR. MORIARTY: Objection. And objection</p> <p>3 form.</p> <p>4 Go ahead and answer if you can. If you</p> <p>5 can.</p> <p>6 BY MR. JONES:</p> <p>7 Q. Yeah. The question is, what opinions are</p> <p>8 you offering in this case? Can you answer that?</p> <p>9 A. My opinions for this case -- well, the</p> <p>10 opinions that I intend to render in this case -- I</p> <p>11 certainly may not be limited to just this report --</p> <p>12 will be that the product of TVT or the TVT pelvic --</p> <p>13 or the Prolene polypropylene mesh, they were not</p> <p>14 defective.</p> <p>15 Q. Okay. Any other opinions you'll be</p> <p>16 rendering in this case?</p> <p>17 MR. MORIARTY: Objection. Form.</p> <p>18 Go ahead.</p> <p>19 BY MR. JONES:</p> <p>20 Q. This is my only opportunity. Like you</p> <p>21 just said, heh, if they're not in my report, you get</p> <p>22 to ask me. Here's my only opportunity to ask you.</p> <p>23 So tell me, besides the opinion that</p> <p>24 you're rendering that the TVT device is not defective</p> <p>25 nor is the Prolene mesh defective, what are the other</p>	<p>1 MR. MORIARTY: Objection.</p> <p>2 Go ahead.</p> <p>3 THE WITNESS: At this point in time, I</p> <p>4 have not been asked to supplement my report. I</p> <p>5 suppose if new information becomes available, I</p> <p>6 reserve the right to supplement my report. But</p> <p>7 based on the current information available to me</p> <p>8 today, my opinions are included in my report.</p> <p>9 BY MR. JONES:</p> <p>10 Q. Okay. Thank you. Perfect. Have you ever</p> <p>11 seen in your practice TVT mesh fray?</p> <p>12 A. I guess my question is -- I mean, that</p> <p>13 term is thrown around so much. What do you mean by</p> <p>14 "fray"?</p> <p>15 Q. Did you review the expert report of</p> <p>16 plaintiff's expert Bruce Rosenzweig?</p> <p>17 A. I don't recall specifically. May I see</p> <p>18 the --</p> <p>19 Q. I don't have the report with me. Do you</p> <p>20 know -- can you tell the jury what TVT mesh fraying</p> <p>21 means to you?</p> <p>22 A. What it means to me? Okay. When put</p> <p>23 under extreme stressors, okay, the -- I mean, extreme</p> <p>24 ex vivo supraphysiologic stressors, you'll see some</p> <p>25 of the ends of the material, I guess, become loose.</p>
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<p>1 opinions you're going to be offering in this case?</p> <p>2 MR. MORIARTY: And besides what's in his</p> <p>3 report?</p> <p>4 THE WITNESS: Well, see, that's it. I</p> <p>5 mean, everything that's in my report I will be</p> <p>6 presenting.</p> <p>7 BY MR. JONES:</p> <p>8 Q. Okay.</p> <p>9 A. In addition to whatever you may choose to</p> <p>10 ask me.</p> <p>11 Q. And I'm asking you right now. Please tell</p> <p>12 me what opinions you're going to be offering in this</p> <p>13 case that you haven't included in your report.</p> <p>14 MR. MORIARTY: Objection. Form.</p> <p>15 Go ahead.</p> <p>16 THE WITNESS: Okay. If you're not going</p> <p>17 to be asking me anything more, then the opinions</p> <p>18 that I'm going to be rendering are in this</p> <p>19 report.</p> <p>20 BY MR. JONES:</p> <p>21 Q. Okay. Do you have any intention to</p> <p>22 supplement your report? Have you been asked to?</p> <p>23 A. I have not been asked to.</p> <p>24 Q. Okay. So at this point, you've not been</p> <p>25 asked by Ethicon to supplement your report?</p>	<p>1 And that's what fraying means to me.</p> <p>2 Q. Okay. Perfect. We've use that definition</p> <p>3 moving forward.</p> <p>4 A. Okay.</p> <p>5 Q. Have you ever seen fraying without extreme</p> <p>6 stress or supraphysiological forces placed on the</p> <p>7 mesh?</p> <p>8 A. Hmm. I have not seen it fray under no</p> <p>9 tension, but that wasn't your question.</p> <p>10 Q. No, it wasn't.</p> <p>11 A. I haven't seen it fray under -- what did</p> <p>12 you ask again?</p> <p>13 MR. JONES: Can you read it back for him?</p> <p>14 (Whereupon the Court Reporter read the</p> <p>15 requested question.)</p> <p>16 THE WITNESS: No.</p> <p>17 BY MR. JONES:</p> <p>18 Q. Okay. Is fraying of TVT mesh inherent in</p> <p>19 the design of the mesh?</p> <p>20 A. Inherent. I mean, I'm serious. I want to</p> <p>21 make sure I get your answer right. What do you mean</p> <p>22 by "inherent"?</p> <p>23 Q. Are you familiar with any internal</p> <p>24 documents that discuss whether fraying is inherent in</p> <p>25 the design of TVT mesh?</p>

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<p>1 A. I've reviewed a lot of documents, and I</p> <p>2 don't remember seeing one that says the word</p> <p>3 "inherent." I mean, if you'd like me to, I can</p> <p>4 review something for you.</p> <p>5 Q. Okay. That wasn't in one of the 10 or 15</p> <p>6 documents?</p> <p>7 A. Not that I recall.</p> <p>8 Q. Okay. Do you know who Marty Weisberg is?</p> <p>9 A. I recall hearing the name, but I don't</p> <p>10 think -- I don't remember meeting him.</p> <p>11 Q. Okay. Do you know what he -- does he work</p> <p>12 for Ethicon?</p> <p>13 A. I believe he worked -- I don't know if he</p> <p>14 works for Ethicon now, but I think he worked for</p> <p>15 Ethicon in the past.</p> <p>16 Q. Do you know what his role was at Ethicon?</p> <p>17 A. No.</p> <p>18 Q. Do you know who Dan Smith is?</p> <p>19 A. Dan Smith, I met, yes.</p> <p>20 Q. Okay. Do you know what his role at</p> <p>21 Ethicon is?</p> <p>22 A. No, I don't know his role.</p> <p>23 Q. Okay. Do you know who Gene Kammerer is?</p> <p>24 A. No.</p> <p>25 Q. Do you know Laura Angelini is?</p>	<p>1 MR. MORIARTY: Objection.</p> <p>2 BY MR. JONES:</p> <p>3 Q. So let me reask the question again.</p> <p>4 A. Okay. Go ahead.</p> <p>5 Q. Have you ever -- is particle loss a risk</p> <p>6 of TVT mesh?</p> <p>7 MR. MORIARTY: Objection. Form.</p> <p>8 THE WITNESS: You know, not when placed</p> <p>9 appropriately.</p> <p>10 BY MR. JONES:</p> <p>11 Q. Have you ever experienced particle loss of</p> <p>12 the TVT mesh when you've used TVT mesh?</p> <p>13 A. No, because I've not put it under any</p> <p>14 significant tension -- any tension.</p> <p>15 Q. Since -- you've used the TVT line of</p> <p>16 products since 2003, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Since your use of the TVT line of products</p> <p>19 since 2003, you've never seen particle loss with TVT</p> <p>20 mesh?</p> <p>21 A. I have.</p> <p>22 Q. Okay. Explain.</p> <p>23 A. When you apply excessive tension to the</p> <p>24 mesh, supraphysiologic stressors, you stretch it out</p> <p>25 like that (indicating), there's going to be -- what</p>
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<p>1 A. I don't recall that name.</p> <p>2 Q. Do you know who David Robinson is?</p> <p>3 A. Yes, I do -- I do know -- I remember</p> <p>4 meeting David Robinson.</p> <p>5 Q. Okay. Do you know who Dan Lamont is?</p> <p>6 MR. MORIARTY: Objection. Now you're just</p> <p>7 throwing out country music.</p> <p>8 THE WITNESS: I don't remember that name.</p> <p>9 I'm sorry. Good. I'm glad. No, I don't</p> <p>10 remember Dan Lamont.</p> <p>11 BY MR. JONES:</p> <p>12 Q. We'll move on. I'm done with the name</p> <p>13 game.</p> <p>14 A. Thank you.</p> <p>15 Q. All right. We'll go back to -- is</p> <p>16 particle loss a risk of TVT mesh?</p> <p>17 MR. MORIARTY: Objection. Form.</p> <p>18 THE WITNESS: Again, you know, you have to</p> <p>19 define for me how -- these terms are very</p> <p>20 loosely used. What do you define by "particle</p> <p>21 loss"?</p> <p>22 BY MR. JONES:</p> <p>23 Q. The mesh losing particles, hence the name</p> <p>24 "particle loss." That's all my definition is.</p> <p>25 A. Right. I got you.</p>	<p>1 do you call it?</p> <p>2 Q. Particle loss?</p> <p>3 A. Particle loss.</p> <p>4 Q. Since your use of TVT mesh dating back to</p> <p>5 2003, have you ever experienced particle loss when</p> <p>6 you've used TVT mesh?</p> <p>7 MR. MORIARTY: Objection. Form.</p> <p>8 Go ahead.</p> <p>9 THE WITNESS: Have -- again, have I -- go</p> <p>10 ahead. Say it again.</p> <p>11 BY MR. JONES:</p> <p>12 Q. Since 2003 --</p> <p>13 A. Got it.</p> <p>14 Q. -- have you experienced particle loss when</p> <p>15 you used TVT mesh?</p> <p>16 A. No, because I didn't place my meshes under</p> <p>17 tension.</p> <p>18 Q. You have never experienced particle loss</p> <p>19 with TVT mesh since 2003, correct?</p> <p>20 MR. MORIARTY: Objection. Asked three</p> <p>21 times.</p> <p>22 Go ahead.</p> <p>23 MR. JONES: Maybe just twice.</p> <p>24 THE WITNESS: Okay. Say it again because</p> <p>25 I want to make sure I answer okay.</p>

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<p>1 BY MR. JONES:</p> <p>2 Q. See this happens.</p> <p>3 A. That's fine. Go ahead.</p> <p>4 Q. So maybe I'm going to ask it again.</p> <p>5 A. All right.</p> <p>6 Q. All right. Since 2003 --</p> <p>7 A. Right.</p> <p>8 Q. -- in all your use of TVT mesh, you've</p> <p>9 never personally experienced particle loss?</p> <p>10 MR. MORIARTY: Objection. Asked and</p> <p>11 answered.</p> <p>12 THE WITNESS: No, because I don't put it</p> <p>13 in under tension.</p> <p>14 MR. JONES: I have to move to strike</p> <p>15 everything after the word "no." Okay.</p> <p>16 Next question. It's just legal, legal</p> <p>17 crud is what it is.</p> <p>18 MR. ROSENBLATT: It doesn't mean anything.</p> <p>19 MR. JONES: Doesn't mean anything to you,</p> <p>20 probably not going to mean anything to any of us</p> <p>21 either.</p> <p>22 BY MR. JONES:</p> <p>23 Q. All right. Moving forward. Since 2003,</p> <p>24 in your use of TVT mesh, have you ever experienced</p> <p>25 TVT mesh roping or curling?</p>	<p>1 Q. Okay. Yes or no: Can TVT mesh cause</p> <p>2 chronic dyspareunia?</p> <p>3 MR. MORIARTY: Objection to form.</p> <p>4 THE WITNESS: Again, I cannot answer that</p> <p>5 specific question.</p> <p>6 BY MR. JONES:</p> <p>7 Q. Yes or no: Can TVT mesh cause chronic</p> <p>8 voiding dysfunction in women?</p> <p>9 MR. MORIARTY: Same objection.</p> <p>10 THE WITNESS: Again, I mean, the way</p> <p>11 you're asking it, I cannot answer that question.</p> <p>12 BY MR. JONES:</p> <p>13 Q. Yes or no: Can TVT mesh cause nerve</p> <p>14 damage in women?</p> <p>15 MR. MORIARTY: Objection.</p> <p>16 THE WITNESS: Again, the way you're asking</p> <p>17 it, I cannot answer that question.</p> <p>18 BY MR. JONES:</p> <p>19 Q. Yes or no: Can TVT mesh cause death in</p> <p>20 patients?</p> <p>21 MR. MORIARTY: I'm sorry. Cause what?</p> <p>22 MR. JONES: Death.</p> <p>23 MR. MORIARTY: D-E-A-T-H.</p> <p>24 MR. JONES: D, starts with a D.</p> <p>25 MR. MORIARTY: D-E-A-T-H?</p>
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<p>1 A. Since 2003, have I experienced, in my use</p> <p>2 of TVT mesh, roping or curling?</p> <p>3 Q. (Nodding head up and down.)</p> <p>4 A. No.</p> <p>5 Q. Since 2003, in your use of TVT mesh, have</p> <p>6 you ever seen the mesh deform without</p> <p>7 supraphysiological tension?</p> <p>8 A. No.</p> <p>9 Q. Can TVT mesh cause chronic pain?</p> <p>10 MR. MORIARTY: Objection. Form.</p> <p>11 THE WITNESS: I mean, I guess -- I kind of</p> <p>12 feel like Bill Clinton here. What do you mean</p> <p>13 by "cause"? Because if you use it in a broad, a</p> <p>14 very broad sense, anything can cause chronic</p> <p>15 pain, in a very broad sense.</p> <p>16 BY MR. JONES:</p> <p>17 Q. I'm going to ask the question in a</p> <p>18 yes-or-no form, and then I'm going to ask if you can</p> <p>19 answer it yes or no.</p> <p>20 Yes or no: Can TVT mesh cause chronic</p> <p>21 pain in women?</p> <p>22 MR. MORIARTY: Objection. Form.</p> <p>23 THE WITNESS: I cannot answer that</p> <p>24 specific question.</p> <p>25 BY MR. JONES:</p>	<p>1 THE WITNESS: D-E-A-T-H?</p> <p>2 MR. JONES: Yes.</p> <p>3 MR. MORIARTY: Objection.</p> <p>4 THE WITNESS: You know what? In the form</p> <p>5 that you're asking it, I can't answer that</p> <p>6 question.</p> <p>7 BY MR. JONES:</p> <p>8 Q. Okay. Do you tell your patients when</p> <p>9 you -- before you implant a TVT device or Ethicon</p> <p>10 mesh product, that you have consulted for Ethicon</p> <p>11 since 2003?</p> <p>12 A. Now?</p> <p>13 Q. We'll start with now.</p> <p>14 A. No.</p> <p>15 Q. Have you ever?</p> <p>16 A. Yes.</p> <p>17 Q. When?</p> <p>18 A. When I was consulting for Ethicon and TVT.</p> <p>19 Q. Okay. So between 2003 -- between 2003 and</p> <p>20 2012, you told your patients you were an Ethicon</p> <p>21 consultant?</p> <p>22 A. It was my usual practice.</p> <p>23 Q. Currently, you don't tell -- currently,</p> <p>24 what do you tell your patients?</p> <p>25 A. I don't tell them I'm a consultant.</p>

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<p>1 Q. Okay. Do you tell them that you're a 2 litigation consultant for Ethicon? 3 A. No. 4 Q. Okay. Do you agree that one of the risks 5 of the TVT mesh is chronic pain? 6 A. I don't attribute it to the mesh. 7 Q. Is that a no? 8 A. I guess we'd say that's no. 9 Q. Do you agree that one of the risks of the 10 TVT mesh is chronic dyspareunia? 11 A. I don't attribute it to the mesh. 12 Q. Is that a no? 13 A. That's a no. 14 Q. Do you agree one of the risks of the TVT 15 device is chronic pain in women? 16 A. I don't attribute it to the device. 17 Q. Is that a no? 18 A. That's a no. 19 Q. Do you agree that one of the risks of the 20 TVT device is chronic dyspareunia? 21 A. I do not attribute it to the device. 22 Q. Is that a no? 23 A. That's a no. 24 Q. Do you agree one of the risks of the TVT 25 mesh is erosion of the mesh through the woman's</p>	<p>1 All right. Is the TVT Retropubic the gold 2 standard? 3 A. Well -- 4 MR. MORIARTY: Objection. 5 Go ahead. 6 THE WITNESS: I have to defer to the AUA, 7 AUGS, and SUFU that have described the 8 polypropylene mid-urethral sling as the gold 9 standard for the treatment -- 10 Now, wait a second. What was your 11 question? 12 BY MR. JONES: 13 Q. Right. 14 A. There you go. 15 Q. Is TVT Retropubic the gold standard? Yes 16 or no. To you. I'm asking you. 17 A. Oh, me? 18 Q. Yeah. 19 A. Me. I wouldn't specifically say the 20 Retropubic. 21 Q. In your opinion, is the TVT-Secur the gold 22 standard? 23 A. I wouldn't say specifically the Secur. 24 Q. In your opinion, is the TVT Obturator the 25 gold standard?</p>
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<p>1 vaginal tissues? 2 A. Restate the question. 3 Q. Sure. 4 MR. JONES: Can you read it back? 5 (Whereupon the Court Reporter read the 6 previous question.) 7 THE WITNESS: The risk of using any mesh 8 is potential erosion. 9 BY MR. JONES: 10 Q. That's a yes, correct? 11 A. That's a yes. 12 Q. Do you agree that TVT mesh that erodes 13 through a woman's vaginal tissue can cause pain to a 14 woman? 15 A. I don't attribute that to the mesh, no. 16 Q. Do you agree TVT mesh that erodes through 17 a woman's vaginal tissue can cause dyspareunia? 18 A. I don't attribute that to the mesh. 19 Q. Do you believe TVT mesh that erodes 20 through a woman's vaginal tissue can cause discomfort 21 to the woman? 22 A. That's pretty broad. What do you want to 23 say is discomfort? I mean, how are you describing 24 "discomfort"? 25 Q. We'll just leave that at that question.</p>	<p>1 A. I would not say specifically the 2 Obturator. 3 Q. In your opinion, is the TVT line of 4 products the gold standard? 5 A. I would not specify it has to be TVT. 6 Q. What is the gold standard, in your 7 opinion? 8 A. In my opinion, the gold standard is the 9 polypropylene mid-urethral sling. 10 Q. Are you a member of AUGS? 11 A. Yeah. 12 Q. When did you join? 13 A. I don't remember. 14 Q. Are you a current member? 15 A. Yes. 16 Q. Are you a current member of SUFU? 17 A. Yes. 18 Q. When was the last time you went to an AUGS 19 convention? 20 A. Hmm. I don't really go to AUGS. 21 Q. When's the last time you went to -- have 22 you ever been to an AUGS convention? 23 A. No. I recently joined since I became 24 board-certified in pelvic reconstructive surgery. 25 Q. You joined AUGS in 2013?</p>

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<p>1 A. Yeah.</p> <p>2 Q. Have you ever attended a SUFU convention?</p> <p>3 A. Yeah.</p> <p>4 Q. How long have you been a member of SUFU?</p> <p>5 A. I've been a member of SUFU since my</p> <p>6 fellowship, somewhere around that time.</p> <p>7 Q. Okay. Do you know Dennis Miller?</p> <p>8 A. Yes.</p> <p>9 Q. How do you know Dennis Miller?</p> <p>10 A. I met him during conferences.</p> <p>11 Q. Do you and Dennis Miller consult together</p> <p>12 for Ethicon?</p> <p>13 A. Do I?</p> <p>14 Q. Have you and Dennis Miller ever acted as</p> <p>15 consultants together for Ethicon?</p> <p>16 A. I believe we were at similar venues, the</p> <p>17 same venues.</p> <p>18 Q. Do you know Howard Goldman?</p> <p>19 A. Yes.</p> <p>20 Q. How do you know Howard Goldman?</p> <p>21 A. I know him professionally from the</p> <p>22 Cleveland Clinic, and I also know him as a preceptor.</p> <p>23 Q. For Ethicon?</p> <p>24 A. For Ethicon.</p> <p>25 Q. Dr. Goldman and you acted as consultant --</p>	<p>1 not a single medical society has specifically called</p> <p>2 out the TVT line of products in any of their society</p> <p>3 statements, correct?</p> <p>4 A. I don't believe so.</p> <p>5 Q. Okay. Do you know what the forces are in</p> <p>6 the pelvis that are placed on the mesh after it's put</p> <p>7 in place?</p> <p>8 MR. MORIARTY: Objection. Form.</p> <p>9 THE WITNESS: You know, I'm sure I've read</p> <p>10 them somewhere, but I don't recall.</p> <p>11 BY MR. JONES:</p> <p>12 Q. Okay. Do you know the average time for a</p> <p>13 medical device to go from the initial stage of</p> <p>14 development to being marketed?</p> <p>15 A. I don't.</p> <p>16 Q. Have you familiar with the principle of</p> <p>17 Stage-Gates in the design development process?</p> <p>18 A. No.</p> <p>19 Q. Do you have any idea how long it takes to</p> <p>20 get a medical device to market?</p> <p>21 A. No.</p> <p>22 Q. Have you reviewed any internal documents</p> <p>23 that discuss Ethicon's --</p> <p>24 A. I'm sorry. What?</p> <p>25 Q. -- that has discussed Ethicon's average</p>
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<p>1 both acted as consultants for Ethicon?</p> <p>2 A. I believe so.</p> <p>3 Q. Okay. How about Erik Rodner?</p> <p>4 A. I know Erik Rodner from the Ross</p> <p>5 fellowship.</p> <p>6 Q. Were you guys there at the same time?</p> <p>7 A. He was earlier.</p> <p>8 Q. Charles Nager?</p> <p>9 A. Who?</p> <p>10 Q. Do you know Charles Nager? Am I</p> <p>11 pronouncing his name right? Dr. Nager?</p> <p>12 A. The name doesn't ring a bell. I don't --</p> <p>13 Q. Has any medical society endorsed the use</p> <p>14 of the TVT line of products?</p> <p>15 MR. MORIARTY: Objection. Form.</p> <p>16 THE WITNESS: Well, there's two issues</p> <p>17 about that question that I need clarified.</p> <p>18 Number one, you specified the TVT line of</p> <p>19 products. And endorsed.</p> <p>20 So I know they haven't specified the TVT</p> <p>21 line of products. And by saying "endorsed," I</p> <p>22 don't know what you mean by that.</p> <p>23</p> <p>24 BY MR. JONES:</p> <p>25 Q. Supported -- so how about this? None --</p>	<p>1 time for a medical device to market?</p> <p>2 A. No.</p> <p>3 Q. Have you reviewed any internal documents</p> <p>4 related to how the TVT Obturator was developed to</p> <p>5 market?</p> <p>6 A. Did you ask internal documents?</p> <p>7 Q. (Nodding head up and down.)</p> <p>8 A. I reviewed a few, but I don't recall</p> <p>9 specifically something about that, no.</p> <p>10 Q. None specifically that spoke to the time</p> <p>11 it took to get TVT-O to market?</p> <p>12 A. No.</p> <p>13 Q. Have you reviewed the contract between</p> <p>14 Ethicon and Dr. Ulf Ulmsten?</p> <p>15 A. No.</p> <p>16 Q. Are you aware of the oxidizing agents</p> <p>17 naturally occurring inside a woman's vagina?</p> <p>18 MR. MORIARTY: Objection. Form.</p> <p>19 Go ahead.</p> <p>20 THE WITNESS: Well, am I aware there are?</p> <p>21 Yes. What they specifically are, I can't say</p> <p>22 with certainty. I mean --</p> <p>23</p> <p>24 BY MR. JONES:</p> <p>25 Q. Sure. But you're aware there's oxidizing</p>

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<p>1 agents inside a vagina?</p> <p>2 A. Yeah.</p> <p>3 Q. And are you aware of what levels they</p> <p>4 occur at?</p> <p>5 A. No.</p> <p>6 Q. Okay. And have you ever reviewed the</p> <p>7 material safety data sheet for the Prolene material</p> <p>8 used in TVT mesh?</p> <p>9 MR. MORIARTY: Objection.</p> <p>10 Go ahead.</p> <p>11 THE WITNESS: I'm sorry. What?</p> <p>12 BY MR. JONES:</p> <p>13 Q. The material safety data sheet for the</p> <p>14 Prolene material used in TVT mesh.</p> <p>15 A. I mean, I've heard about it, but I've</p> <p>16 never actually seen it.</p> <p>17 Q. Okay. That's not something Ethicon --</p> <p>18 Ethicon provided to you?</p> <p>19 A. I've heard about it, but I've never seen</p> <p>20 it.</p> <p>21 Q. So no?</p> <p>22 A. No.</p> <p>23 Q. If you have your CV in front of you?</p> <p>24 A. Yep.</p> <p>25 Q. First question, you've redacted the</p>	<p>1 mesh for Ethicon?</p> <p>2 A. Not that I recall.</p> <p>3 Q. Do you have a site coordinator set up for</p> <p>4 studies like that that you would use?</p> <p>5 A. No.</p> <p>6 Q. Okay. You listed lab director from 2012</p> <p>7 to present at Southside Urology. What does lab</p> <p>8 director entail?</p> <p>9 A. We have a CLIA-certified lab as part of</p> <p>10 the practice, and one of the clinicians basically</p> <p>11 gets specially trained to oversee the lab,</p> <p>12 CLIA-trained.</p> <p>13 Q. What does CLIA-trained mean?</p> <p>14 A. C-L-E-A. Clinical Laboratory something</p> <p>15 Association. I don't know.</p> <p>16 Q. Okay. Are you conducting any current</p> <p>17 research on polypropylene mesh?</p> <p>18 A. No.</p> <p>19 Q. Have you ever published any peer review</p> <p>20 articles on TVT mesh?</p> <p>21 A. I may have early on in my career as</p> <p>22 general reviews.</p> <p>23 Q. Have you ever published any article on the</p> <p>24 TVT device in a peer-reviewed journal?</p> <p>25 A. Could you repeat the question? I want to</p>
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<p>1 address for Southside Urology.</p> <p>2 What is the address of Southside Urology,</p> <p>3 just for the record?</p> <p>4 A. Okay. There's a PO box and a mailing</p> <p>5 address. I don't know what the PO box is. The</p> <p>6 mailing address is 1040 Main Street, Danville,</p> <p>7 Virginia 24541.</p> <p>8 Q. Is -- do you list the same address for the</p> <p>9 Piedmont Continence Institute?</p> <p>10 A. Piedmont Institute for Continence and</p> <p>11 Urinary Control, yes.</p> <p>12 Q. Where did you grow up?</p> <p>13 A. Born in Brooklyn. Till fifth grade.</p> <p>14 Moved to New Jersey, through high school. Went to</p> <p>15 St. Louis for medical school, residency -- for</p> <p>16 undergrad, medical school and residency. Year in Los</p> <p>17 Angeles, and here in Danville.</p> <p>18 Q. Have you done any studies for Ethicon?</p> <p>19 A. Early on -- and I mean, like in 2000, I</p> <p>20 may have done a study. I don't even remember the</p> <p>21 details of it.</p> <p>22 Q. Okay. Have you done -- other than that,</p> <p>23 have you done any study for Ethicon that you recall?</p> <p>24 A. Not that I recall.</p> <p>25 Q. Have you ever done a study on the TVT-O</p>	<p>1 get it right.</p> <p>2 Q. Yeah. I'm just getting them -- just</p> <p>3 getting to the bottom of what you've published, what</p> <p>4 you've written on, what you haven't.</p> <p>5 A. I gotcha.</p> <p>6 Q. If it helps, I'll cut it off at 2002. I'm</p> <p>7 look at your résumé right now.</p> <p>8 A. All right.</p> <p>9 Q. Have you ever published any peer-reviewed</p> <p>10 article on TVT mesh?</p> <p>11 A. Since 2002? Is that what you meant by cut</p> <p>12 it off from 2002?</p> <p>13 Q. Sure.</p> <p>14 A. Like, from 2002 onward?</p> <p>15 Q. Sure.</p> <p>16 A. No.</p> <p>17 Q. What is the 2002 article that you</p> <p>18 published on TVT mesh?</p> <p>19 A. Where is that? There's my reports. Are</p> <p>20 you looking at the same CV I am?</p> <p>21 Q. Just don't steal all my awesome notes on</p> <p>22 it.</p> <p>23 A. I'm sorry. I apologize. These are</p> <p>24 lectures, courses.</p> <p>25 Q. If you can go to the next page.</p>

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<p>1 A. 2002. This is April 2000.</p> <p>2 Q. Is that a different CV?</p> <p>3 A. No, but this article --</p> <p>4 MR. MORIARTY: No, but the question seemed</p> <p>5 to build in 2002.</p> <p>6 BY MR. JONES:</p> <p>7 Q. Yeah, the question is --</p> <p>8 MR. MORIARTY: And this is 2000.</p> <p>9 THE WITNESS: This is an article from</p> <p>10 2000.</p> <p>11 BY MR. JONES:</p> <p>12 Q. I'm asking you what article are you</p> <p>13 referencing in 2002 that you published on TVT?</p> <p>14 A. Oh, I didn't reference an article. Did I?</p> <p>15 I apologize if I mis --</p> <p>16 Q. Okay. What article are you referencing at</p> <p>17 all that you published on TVT?</p> <p>18 A. Oh, the Comiter article may have included</p> <p>19 TVT.</p> <p>20 What I'm saying is, if you're asking me</p> <p>21 have I had an article solely on TVT? No. I said, in</p> <p>22 the context of a review article, I perhaps discussed</p> <p>23 TVT, and that's the review article I remembered, was</p> <p>24 the 2000 April, Surgical Treatment of Female Stress</p> <p>25 Urinary Incontinence (Reading) -- Contemporary</p>	<p>1 Q. Have you ever studied polypropylene mesh</p> <p>2 and reported on it in a peer review journal?</p> <p>3 A. So you used the word "and." So studied</p> <p>4 and reported?</p> <p>5 Q. (Nodding head up and down.)</p> <p>6 A. No.</p> <p>7 Q. Have you ever published any peer review</p> <p>8 journal articles on the Burch procedure other than</p> <p>9 the 2000 review article?</p> <p>10 A. No.</p> <p>11 Q. Do you have any current research ongoing</p> <p>12 today on any product?</p> <p>13 A. No.</p> <p>14 Q. Do you consider yourself an academic</p> <p>15 physician?</p> <p>16 MR. MORIARTY: Objection. Form.</p> <p>17 THE WITNESS: Well, "define academic."</p> <p>18 BY MR. JONES:</p> <p>19 Q. Are you an expert in chemical engineering?</p> <p>20 A. No.</p> <p>21 Q. Expert in pathology?</p> <p>22 A. Well, I'll even go back to the other</p> <p>23 question. Define "expert." I mean, am I an expert</p> <p>24 in pathology? Do I have a Ph.D. in pathology? Or</p> <p>25 have I -- have I, do I know pathology as I practice</p>
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<p>1 Urology. And I'm sure at that point we talked about</p> <p>2 TVT.</p> <p>3 Q. Is that a peer-reviewed journal?</p> <p>4 A. Contemporary Urology, I think is.</p> <p>5 Q. Is it still published today? Is it still</p> <p>6 around?</p> <p>7 A. I believe so. I believe so.</p> <p>8 MR. MORIARTY: That's why it's called</p> <p>9 contemporaneous -- Contemporary Urology.</p> <p>10 MR. JONES: In 2000?</p> <p>11 MR. MORIARTY: It's still contemporary.</p> <p>12 THE WITNESS: That's the article I was</p> <p>13 referring to. In answer to your question, that</p> <p>14 was the -- in answer, direct answer to your</p> <p>15 question, that article probably included TVT in</p> <p>16 it.</p> <p>17 BY MR. JONES:</p> <p>18 Q. Got it. Other than the 2000 review</p> <p>19 article in the Contemporary Urology journal, have you</p> <p>20 ever published anything on the TVT mesh?</p> <p>21 A. No.</p> <p>22 Q. Other than the 2000 article that's a</p> <p>23 review article, have you ever published anything on</p> <p>24 polypropylene mesh?</p> <p>25 A. No.</p>	<p>1 it in my practice? Have I reviewed pathologic</p> <p>2 slides? Have I done a lab rotation for a year at</p> <p>3 Washington University looking at pathology? In that</p> <p>4 context, I have expertise in pathology.</p> <p>5 Q. Have you ever reviewed pathology slides of</p> <p>6 TVT mesh?</p> <p>7 A. I may have gone down to the pathology</p> <p>8 department and looked at some of my explants, yes.</p> <p>9 Q. Okay. You don't have any specific</p> <p>10 recollection of which explants you reviewed?</p> <p>11 A. No.</p> <p>12 Q. Do you have any records of the pathology</p> <p>13 slides that you reviewed?</p> <p>14 A. I mean --</p> <p>15 Q. Do you know what --</p> <p>16 A. There are clinical records of all the</p> <p>17 pathology that I've submitted.</p> <p>18 Q. Do you know one way or the other, any way</p> <p>19 in determining what pathology slides you reviewed</p> <p>20 related to TVT mesh?</p> <p>21 A. Oh, I see what you're saying.</p> <p>22 Q. Right.</p> <p>23 A. So specifically the ones I reviewed. No.</p> <p>24 I mean, I -- there's -- there's reports on all of</p> <p>25 them. There's pathologic report on everything.</p>

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<p>1 Q. Okay. But if we wanted to know which ones</p> <p>2 you looked at, no dice, not going to happen?</p> <p>3 A. I can't provide you with that.</p> <p>4 Q. Okay. Do you have any background in</p> <p>5 polymer chemistry?</p> <p>6 A. Again, I don't have a Ph.D., no.</p> <p>7 Q. Have you ever done bench research on</p> <p>8 polypropylene mesh?</p> <p>9 A. Bench research? No.</p> <p>10 Q. Lab research on polypropylene mesh?</p> <p>11 A. Lab research? No.</p> <p>12 Q. Your opinion that TVT mesh does not</p> <p>13 degrade in vivo, have you ever attempted to have that</p> <p>14 opinion published in a peer review journal?</p> <p>15 A. No.</p> <p>16 Q. Any of the opinions that you'll be</p> <p>17 offering in this litigation, have you ever attempted</p> <p>18 to have published in a peer review journal?</p> <p>19 A. No.</p> <p>20 Q. Are the opinions you're offering in this</p> <p>21 litigation solely for litigation purposes?</p> <p>22 MR. MORIARTY: Objection.</p> <p>23</p> <p>24 BY MR. JONES:</p> <p>25 Q. I'll withdraw it.</p>	<p>1 Q. Thank you. Do you -- are you aware the</p> <p>2 industry standards that govern what warnings must be</p> <p>3 in an IFU?</p> <p>4 A. The industry standards? No, I don't know</p> <p>5 that --</p> <p>6 Q. Do you agree that all material risks</p> <p>7 related to the TVT mesh must be included in the IFU?</p> <p>8 MR. MORIARTY: Objection. Form.</p> <p>9 THE WITNESS: I guess define "material</p> <p>10 risk."</p> <p>11 BY MR. JONES:</p> <p>12 Q. It's in your report. How do you use it?</p> <p>13 I'm using your term.</p> <p>14 A. I understand. I just wanted to know on</p> <p>15 how you were using it in your question.</p> <p>16 (Off record discussion.)</p> <p>17 Q. I wish I could let you take all day,</p> <p>18 Doctor, but we're on a tight time frame.</p> <p>19 A. I apologize. I just don't see where I</p> <p>20 write on this TVT IFU section the term "material</p> <p>21 risk." If you would like to point out to me</p> <p>22 specifically where I'm using it, I'll be happy to cut</p> <p>23 to the chase for you.</p> <p>24 Q. Yeah. Why don't you go to page 4? First</p> <p>25 sentence, page 4.</p>
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<p>1 Are you an expert on warnings?</p> <p>2 A. I'm sorry?</p> <p>3 Q. I'll withdraw that last question. Are you</p> <p>4 an expert on warnings?</p> <p>5 A. Warnings?</p> <p>6 Q. Warnings related to TVT mesh.</p> <p>7 A. Warnings related to TVT mesh. I'm trying</p> <p>8 to consider what an expert in warnings would be.</p> <p>9 Again, I don't know what an expert in warnings would</p> <p>10 be.</p> <p>11 Q. Have you ever drafted an IFU?</p> <p>12 A. No.</p> <p>13 Q. Do you rely in your normal course of</p> <p>14 practice as a physician on IFUs?</p> <p>15 A. Do I rely?</p> <p>16 Q. (Nodding head up and down.)</p> <p>17 A. No.</p> <p>18 Q. Do you review IFUs before you use the</p> <p>19 product?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Always?</p> <p>22 A. Which product?</p> <p>23 Q. Any product.</p> <p>24 A. It is my usual practice to review IFUs</p> <p>25 before using a new product.</p>	<p>1 A. Oh. That's under the section of informed</p> <p>2 consent. Okay. Let me look at that.</p> <p>3 Q. So I'm using your term "material risk."</p> <p>4 Okay?</p> <p>5 A. Okay. But that --</p> <p>6 Q. See that? You see the words?</p> <p>7 A. But that -- yeah, I see the word right</p> <p>8 there.</p> <p>9 Q. All right. Let me ask my question.</p> <p>10 A. Go ahead.</p> <p>11 Q. Is it your opinion that the TVT IFU should</p> <p>12 include all material risks associated with the</p> <p>13 device?</p> <p>14 MR. MORIARTY: Objection.</p> <p>15 THE WITNESS: And I know we're under a</p> <p>16 time restraint, so I'll respect that by</p> <p>17 answering I can't answer your question, because</p> <p>18 I use the term "material risk" in my discussion</p> <p>19 on informed consent between surgeon and</p> <p>20 patients, not on the discussion in an IFU. I</p> <p>21 use the term differently.</p> <p>22 So if you want to define what you mean by</p> <p>23 "material risk in an IFU," I'll be happy to try</p> <p>24 to answer your question.</p> <p>25 BY MR. JONES:</p>

32 (Pages 122 to 125)

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<p>1 Q. Same what you mean in your report when 2 you're discussing it in that section. That's what I 3 mean. 4 A. Oh, I understand. 5 Q. So same question, yes or no. Does the IFU 6 for the TVT need to include all material risks 7 associated with the device? Yes or no or I can't 8 answer the question? 9 MR. MORIARTY: Objection. Form. 10 Go ahead. 11 THE WITNESS: I can't answer the question 12 for IFUs. 13 BY MR. JONES: 14 Q. Does the TVT IFU need to include all risks 15 associated with the device? Yes or no or I can't 16 answer the question? 17 MR. MORIARTY: Objection. Form. Go 18 ahead. 19 THE WITNESS: No. 20 BY MR. JONES: 21 Q. What risk must be included in the TVT IFU? 22 A. The material -- I'm sorry. The risk 23 unique to the device. The risks unique to the 24 device. 25 Q. All --</p>	<p>1 A. Correct. 2 Q. Okay. What risks are unique to the TVT 3 device that need to be in the TVT IFU? 4 MR. MORIARTY: Objection. Form. 5 Go ahead. 6 THE WITNESS: The unique risks to the TVT 7 device is erosion of the mesh material. 8 BY MR. JONES: 9 Q. Is erosion of the mesh material the only 10 unique device -- or unique risk associated with the 11 TVT device? 12 A. In my opinion, yes. 13 Q. If erosion is the only risk listed in the 14 TVT IFU, is the TVT IFU adequate, in your opinion? 15 MR. MORIARTY: Objection. Form. 16 THE WITNESS: I know you're on a time 17 constraint, but I'd like to look specifically at 18 the TVT IFU that you're speaking about. 19 MR. MORIARTY: He just asked a 20 hypothetical. 21 THE WITNESS: I'm sorry? What -- 22 MR. JONES: I think that was an objection. 23 I'm not for sure, though. 24 MR. MORIARTY: I did object. 25 MR. JONES: That was an objection?</p>
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<p>1 A. The risks unique to the proper use of the 2 device. 3 Q. It's your opinion all risk unique to the 4 TVT device, specifically proper use of the TVT 5 device, must be included in the TVT IFU, correct? 6 MR. MORIARTY: Objection. Form. 7 THE WITNESS: Read it back again. I just 8 want to make sure. 9 MR. JONES: I'm going fast because I'm on 10 a tight -- 11 THE WITNESS: I'm with you. I'm sorry. I 12 apologize. I want to make sure it's right. 13 MR. JONES: Can you read that question 14 back? 15 (Whereupon the Court Reporter read the 16 requested question.) 17 THE WITNESS: All risks unique to the TVT 18 device. 19 Yeah, I think that's -- if that's what I 20 said, yeah, that's what I mean. 21 BY MR. JONES: 22 Q. It's your opinion that, the risks 23 associated with the device is caused by improper use 24 of the device, that risk does not need to be in the 25 IFU, correct?</p>	<p>1 MR. MORIARTY: No. I objected before I 2 got out of my seat. 3 MR. JONES: Okay. I was talking about 4 what you said just then. 5 BY MR. JONES: 6 Q. I'll ask the question again. 7 A. Go ahead. 8 Q. Okay. 9 A. Go ahead. 10 MR. MORIARTY: No, wait. 11 MR. JONES: Let me ask my question. Is 12 that okay? 13 MR. MORIARTY: Yeah. 14 BY MR. JONES: 15 Q. Is erosion the only unique risk associated 16 with the TVT device? Yes or no? 17 MR. MORIARTY: Objection. Form. 18 Go ahead. 19 And asked and answered. 20 THE WITNESS: Yes. 21 BY MR. JONES: 22 Q. Okay. If the TVT IFU device only includes 23 erosion as the unique risk associated with TVT -- 24 A. You got a lot detail there. If the TVT 25 IFU --</p>

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<p>1 Q. -- only includes erosion as a risk of the</p> <p>2 device, is the IFU adequate?</p> <p>3 A. -- only includes erosion of the TVT</p> <p>4 device. I mean, in a sense, yeah.</p> <p>5 Q. In the cadaver labs in educational courses</p> <p>6 that you've done for Ethicon, have you ever taught</p> <p>7 anything that is contradicted by the product IFU?</p> <p>8 A. Not that I'm aware of.</p> <p>9 Q. So it's fair to say the information you</p> <p>10 give to surgeons in these educational labs and</p> <p>11 seminars are consistent with the content in the</p> <p>12 instructions for use for that device?</p> <p>13 A. Yes.</p> <p>14 Q. Have you ever appeared in any marketing</p> <p>15 videos for Ethicon?</p> <p>16 A. I don't recall. I don't recall being</p> <p>17 asked either.</p> <p>18 Q. Okay. You have no recollection of Ethicon</p> <p>19 getting your approval for your use of -- of your</p> <p>20 likeness in their marketing videos?</p> <p>21 A. No, not that I'm aware.</p> <p>22 Q. Okay. Describe to the jury what a normal</p> <p>23 week in the life of Dr. Carbone is.</p> <p>24 A. Define "normal."</p> <p>25 Q. Limiting it to -- here's what I'm looking</p>	<p>1 A. 20 to 25 percent.</p> <p>2 Q. Before 2011, what percentage of your</p> <p>3 practice was related to operating on patients for</p> <p>4 stress urinary incontinence?</p> <p>5 A. Maybe 30, 35 percent.</p> <p>6 Q. Over the past three years, your usage of</p> <p>7 transvaginal mesh has decreased, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Over the past three years, your usage of</p> <p>10 TVT mesh has decreased, correct?</p> <p>11 A. Yes.</p> <p>12 Q. You no longer use transvaginal mesh to</p> <p>13 treat pelvic organ prolapse whatsoever, correct?</p> <p>14 A. Correct.</p> <p>15 Q. Have you ever used any mesh products</p> <p>16 transvaginally since the year 2000 that are not made</p> <p>17 by Ethicon?</p> <p>18 A. No.</p> <p>19 Q. Do you treat mesh complications?</p> <p>20 A. Yes.</p> <p>21 Q. What percentage of your practice is</p> <p>22 related to mesh -- treating mesh complications?</p> <p>23 A. A very small amount. Less than 5 percent.</p> <p>24 Q. How many -- have you removed mesh from a</p> <p>25 patient before?</p>
Page 131	Page 133
<p>1 for.</p> <p>2 A. Okay. Thanks.</p> <p>3 Q. What you do when you go in as a doctor</p> <p>4 Monday through Friday, or Monday through Sunday.</p> <p>5 A. I kind of feel like you told me I was</p> <p>6 under a time constraint.</p> <p>7 Q. How about this? What percentage of your</p> <p>8 practice is related to evaluating patients with</p> <p>9 stress urinary incontinence?</p> <p>10 A. 25 to 30 percent.</p> <p>11 Q. What percentage of your practice as an</p> <p>12 urologist involves treating males?</p> <p>13 A. 30 percent.</p> <p>14 Q. Okay. What percentage of your practice</p> <p>15 involves operating on patients with stress urinary</p> <p>16 incontinence?</p> <p>17 A. I guess you'd -- I'd have to ask you, is</p> <p>18 this before all the litigation or since all the</p> <p>19 litigation?</p> <p>20 Q. Today.</p> <p>21 A. Today.</p> <p>22 Q. Today, how about -- let me ask the</p> <p>23 question. Today, what percentage of your practice</p> <p>24 involves operating on patients related to stress</p> <p>25 urinary incontinence?</p>	<p>1 A. Yes.</p> <p>2 Q. How many times?</p> <p>3 A. I can't give you an exact count. Slings?</p> <p>4 I'm sorry?</p> <p>5 Q. I was telling him to cut me off on time</p> <p>6 whenever.</p> <p>7 A. I apologize. I thought you were talking</p> <p>8 about the question.</p> <p>9 Q. Sorry.</p> <p>10 A. 40 or 50, I guess, in -- now, what -- let</p> <p>11 me ask you. What is the time frame you're asking?</p> <p>12 Q. Your entire career.</p> <p>13 A. What did I say?</p> <p>14 Q. 40 or 50.</p> <p>15 A. 40 or 50. Yeah, that's right. That's</p> <p>16 about right.</p> <p>17 Q. Of those 40 to 50 mesh products you have</p> <p>18 removed from women, how many are Ethicon mesh</p> <p>19 products?</p> <p>20 A. Most of them. I can't give you a number.</p> <p>21 Q. In your role as a consultant for Ethicon,</p> <p>22 have you trained sales representatives for Ethicon?</p> <p>23 A. Yes.</p> <p>24 Q. Have you participated in what's called the</p> <p>25 Gynecare sales school?</p>

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<p>1 A. I think that's what I was referring to,</p> <p>2 yes.</p> <p>3 Q. Okay. How long did you participate in the</p> <p>4 Gynecare sales school?</p> <p>5 A. I don't remember how many -- I don't</p> <p>6 remember, but I did participate.</p> <p>7 Q. Explain to the jury what your role in the</p> <p>8 Gynecare sales school was.</p> <p>9 A. What I did at the Gynecare sales school</p> <p>10 was to discuss the condition that was appropriate --</p> <p>11 I'm sorry -- the conditions that the product was</p> <p>12 intended to be used for.</p> <p>13 Q. Did you see your role in the Gynecare</p> <p>14 sales school as assisting in the education of Ethicon</p> <p>15 sales reps?</p> <p>16 A. Assist. What do you mean by "assist"?</p> <p>17 Like taught them about the pathophysiology of the</p> <p>18 disease, rare -- I mean, that's what I taught them</p> <p>19 about.</p> <p>20 Q. And when you taught Ethicon sales reps in</p> <p>21 the Gynecare sales school, did you do your best to</p> <p>22 deliver accurate information to Ethicon sales</p> <p>23 representatives?</p> <p>24 A. On the disease process, yes.</p> <p>25 Q. Did you ever describe the obturator space</p>	<p>1 Q. (Nodding head up and down.)</p> <p>2 A. Not that I recall.</p> <p>3 Q. Have you ever given feedback to Ethicon on</p> <p>4 partially absorbable mesh?</p> <p>5 A. No.</p> <p>6 Q. Do you know who Dr. Aaron Kirkemo is?</p> <p>7 A. Yeah, I do.</p> <p>8 Q. You don't have any recollection of having</p> <p>9 conversations with Dr. Kirkemo about partially</p> <p>10 absorbable mesh used in TVT?</p> <p>11 A. No, I -- well, there may have been</p> <p>12 conversations, but I don't -- your first question was</p> <p>13 regarding feedback. But I may have had conversations</p> <p>14 with him.</p> <p>15 Q. Okay. No feedback from any innovation</p> <p>16 council or cadaver lab on partially absorbable mesh</p> <p>17 used in TVT that you recall as you sit here?</p> <p>18 A. That I recall, no.</p> <p>19 Q. How many Ethicon annual summits have you</p> <p>20 attended?</p> <p>21 A. I don't remember.</p> <p>22 Q. Did you attend Ethicon annual summit in</p> <p>23 NAPA Valley?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. How many days were you in NAPA</p>
Page 135	Page 137
<p>1 to Ethicon sales reps in the Gynecare sales school as</p> <p>2 the black hole of the vagina?</p> <p>3 MR. MORIARTY: Objection.</p> <p>4 THE WITNESS: No.</p> <p>5 BY MR. JONES:</p> <p>6 Q. Okay. Is it true that in the year 2010 in</p> <p>7 your role as a consultant for Ethicon, over 50 days</p> <p>8 out of the calendar year you performed consultant</p> <p>9 work for Ethicon?</p> <p>10 A. I'm sorry. 50 days in 2010?</p> <p>11 Q. (Nodding head up and down.)</p> <p>12 A. I wouldn't have -- I -- I don't have an</p> <p>13 accurate number on that. I can't say either way.</p> <p>14 Q. Okay. Is it true that in the year 2010,</p> <p>15 in your role as a consultant for Ethicon, you were</p> <p>16 paid \$100,000?</p> <p>17 A. What year was that?</p> <p>18 Q. 2010.</p> <p>19 A. No.</p> <p>20 Q. Have you ever participated in Project</p> <p>21 Scion for Ethicon?</p> <p>22 A. No, it doesn't ring a bell.</p> <p>23 Q. Okay. Have you ever evaluated partially</p> <p>24 absorbable mesh in Ethicon cadaver labs?</p> <p>25 A. Evaluated?</p>	<p>1 Valley for the Ethicon summit?</p> <p>2 A. Was it a weekend? I don't know.</p> <p>3 Q. Do you recall what year it was?</p> <p>4 A. No.</p> <p>5 Q. Did you go -- did you go to the Ethicon</p> <p>6 summit in NAPA Valley by yourself?</p> <p>7 A. No. There were other people there.</p> <p>8 Q. Okay. Did you travel with any of your</p> <p>9 family members?</p> <p>10 A. I don't think so.</p> <p>11 Q. Didn't take your wife?</p> <p>12 A. I don't believe so.</p> <p>13 Q. Did you attend the Ethicon annual summit</p> <p>14 in Kissimmee, Florida?</p> <p>15 A. Maybe.</p> <p>16 Q. Attend --</p> <p>17 A. I don't know. Because there's a lot of</p> <p>18 programs that are done, kind of at Walt Disney World.</p> <p>19 So I don't remember if it was specifically an Ethicon</p> <p>20 program.</p> <p>21 Q. I'm going to name a list of cities --</p> <p>22 A. Okay.</p> <p>23 Q. -- and you tell me whether Ethicon has</p> <p>24 paid for your travel to those cities as part of your</p> <p>25 role as a consultant for the company.</p>

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<p>1 A. Okay.</p> <p>2 Q. NAPA Valley?</p> <p>3 A. Yes.</p> <p>4 Q. Miami?</p> <p>5 A. Yes.</p> <p>6 Q. Orlando Walt Disney World?</p> <p>7 A. I don't recall.</p> <p>8 Q. Salt Lake City?</p> <p>9 A. Yes.</p> <p>10 Q. Chicago?</p> <p>11 A. I don't recall.</p> <p>12 Q. Las Vegas?</p> <p>13 A. I don't recall. I don't think so.</p> <p>14 Q. San Diego?</p> <p>15 A. I don't recall.</p> <p>16 Q. Paris, France?</p> <p>17 A. Yes.</p> <p>18 Q. New York City?</p> <p>19 A. I don't recall.</p> <p>20 Q. How many times have you visited Ethicon</p> <p>21 headquarters?</p> <p>22 A. I don't remember.</p> <p>23 Q. More than five?</p> <p>24 A. Yes.</p> <p>25 Q. More than ten?</p>	<p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it.</p> <p>10 You are signing same subject</p> <p>11 to the changes you have noted on the</p> <p>12 errata sheet, which will be attached to</p> <p>13 your deposition.</p> <p>14 It is imperative that you</p> <p>15 return the original errata sheet to the</p> <p>16 deposing attorney within thirty (30) days</p> <p>17 of receipt of the deposition transcript</p> <p>18 by you. If you fail to do so, the</p> <p>19 deposition transcript may be deemed to be</p> <p>20 accurate and may be used in court.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
Page 139	Page 141
<p>1 A. You're getting foggy now. I'm not sure.</p> <p>2 Q. It's fair to say you've visited Ethicon</p> <p>3 headquarters more than five times?</p> <p>4 A. Yes.</p> <p>5 Q. The Gynecare sales school where you spoke</p> <p>6 to Ethicon sales representatives, was that at Ethicon</p> <p>7 headquarters?</p> <p>8 A. Yes.</p> <p>9 Q. Where are Ethicon's headquarters?</p> <p>10 A. New Jersey.</p> <p>11 MR. JONES: I think that is all the time I</p> <p>12 have, Dr. Carbone. That wraps up the three</p> <p>13 hours of the TVT deposition. I think we'll take</p> <p>14 a break.</p> <p>15 (Off record discussion.)</p> <p>16 (Carbone 7 was marked for identification and</p> <p>17 not referred to.)</p> <p>18 (Time: 9:00 p.m.)</p> <p>19 (Signature reserved.)</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 - - - - -</p> <p>2 E R R A T A</p> <p>3 - - - - -</p> <p>4</p> <p>5 PAGE LINE CHANGE</p> <p>6</p> <p>7 REASON: _____</p> <p>8</p> <p>9 REASON: _____</p> <p>10</p> <p>11 REASON: _____</p> <p>12</p> <p>13 REASON: _____</p> <p>14</p> <p>15 REASON: _____</p> <p>16</p> <p>17 REASON: _____</p> <p>18</p> <p>19 REASON: _____</p> <p>20</p> <p>21 REASON: _____</p> <p>22</p> <p>23 REASON: _____</p> <p>24</p> <p>25 REASON: _____</p>

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## ACKNOWLEDGMENT OF DEPONENT

I, \_\_\_\_\_, do  
 hereby certify that I have read the  
 foregoing pages, and that the same is  
 a correct transcription of the answers  
 given by me to the questions therein  
 propounded, except for the corrections or  
 changes in form or substance, if any,  
 noted in the attached Errata Sheet.

\_\_\_\_\_  
 JOSEPH M. CARBONE, M.D.      DATE

Subscribed and sworn  
 to before me this  
 \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.  
 My commission expires: \_\_\_\_\_

\_\_\_\_\_  
 Notary Public

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## CERTIFICATE

I, Karen K. Kidwell, RMR, CRR, in and for  
 the Commonwealth of Virginia, do hereby certify that  
 there came before me on Wednesday, March 16, 2016, the  
 person hereinbefore named, who was by me duly sworn to  
 testify to the truth and nothing but the truth of his  
 knowledge concerning the matters in controversy in this  
 cause; that the witness was thereupon examined under  
 oath, the examination reduced to typewriting under my  
 direction, and the deposition is a true record of the  
 testimony given by the witness.

I further certify that I am neither attorney  
 or counsel for, nor related to or employed by, any  
 attorney or counsel employed by the parties hereto or  
 financially interested in the action.

This the 18th day of March, 2016.

\_\_\_\_\_  
 Karen K. Kidwell, RMR, CRR  
 Notary Public #7625774  
 My Commission Expires: 9/30/2019

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Golkow Technologies, Inc. - 1.877.370.DEPS

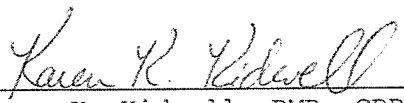
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I, Karen K. Kidwell, RMR, CRR, in and for  
the Commonwealth of Virginia, do hereby certify that  
there came before me on Wednesday, March 16, 2016, the  
person hereinbefore named, who was by me duly sworn to  
testify to the truth and nothing but the truth of his  
knowledge concerning the matters in controversy in this  
cause; that the witness was thereupon examined under  
oath, the examination reduced to typewriting under my  
direction, and the deposition is a true record of the  
testimony given by the witness.

I further certify that I am neither attorney  
or counsel for, nor related to or employed by, any  
attorney or counsel employed by the parties hereto or  
financially interested in the action.

This the 18th day of March, 2016.

  
\_\_\_\_\_  
Karen K. Kidwell, RMR, CRR  
Notary Public #7625774

My Commission Expires: 9/30/2019